

EXHIBIT 49

Page 1

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3
4

5 IN RE JOHNSON & JOHNSON)
6 TALCUM POWDER PRODUCTS) MDL NO.
7 MARKETING, SALES PRACTICES AND) 16-2738 MAS RLS
8 PRODUCTS LIABILITY LITIGATION)
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13 DEPOSITION OF MICHELE L. COTE, PH.D., M.P.H.
14
15
16

17 The deposition upon oral examination of
18 MICHELE L. COTE, PH.D., M.P.H., a witness produced
19 and sworn before Wendi Kramer Sulkoske, Notary Public
20 in and for the County of Boone, State of Indiana,
21 taken on behalf of the Defendant at Faegre Drinker
22 Biddle & Reath, 300 North Meridian Street, Suite
23 2500, Indianapolis, Marion County, Indiana on March
24 21, 2024, pursuant to the Applicable Rules of
25 Procedure.

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4 Michelle A. Parfitt			4 Exhibit 17 The Effect of Talc Particles on 204		
5 Patrick Lyons (Via Zoom)			5 Phagocytes in Co-Culture With Ovarian		
6 1825 K Street, N.W.			6 Cancer		
7 Washington, D.C. 20006			6 Exhibit 18 Molecular Basis Supporting the 205		
8 mparfitt@ashcraftlaw.com			7 Association of Talcum Powder Use With		
9 plyons@ashcraftlaw.com			7 Increased Risk of Ovarian Cancer		
10 BEASLEY ALLEN			8 Exhibit 19 Screening Assessment April 2021 228		
11 P. Leigh O'Dell			9 Health Canada		
12 218 Commerce Street					
13 Montgomery, Alabama 36103					
14 leigh.odell@beasleyallen.com					
15 LEVIN PAPANTONIO RAFFERTY			10 Exhibit 20 Association of Powder Use in the 241		
16 Christopher V. Tisi			10 Genital Area With Risk of Ovarian Cancer		
17 316 South Baylen Street			11 Exhibit 21 Association Between Body Powder Use 255		
18 Pensacola, Florida 32502			11 and Ovarian Cancer: The African-American		
19 ctisi@levinlaw.com			12 Cancer Epidemiology Study		
20 ANAPOL WEISS			13 Exhibit 22 Use of Powder in the Genital Area and 259		
21 Tracy A. Finken (Via Zoom)			13 Ovarian Cancer Risk Examining the		
22 18th Street, suite 1600			14 Evidence		
23 Philadelphia, Pennsylvania 19103			15 Exhibit 23 Excerpt JAMA May 26, 2020 277		
24 tfinken@anapolweiss.com			16 Exhibit 24 Talc, Body Powder, and Ovarian Cancer: 281		
25 FOR THE DEFENDANT:			17 A Summary of the Epidemiologic Evidence		
1 SHOOK HARDY & BACON					
2 Scott A. James			18 Exhibit 25 Association Between the Frequent Use of 294		
3 600 Travis Street, Suite 3400			18 Perineal Talcum Powder Products and		
4 Houston, Texas 77002			18 Ovarian Cancer: A Systematic Review		
5 sjames@shb.com			19 and Meta-analysis		
6 EXAMINATION INDEX			20 Exhibit 26 The Environment and Disease: 309		
7 Page			20 Association or Causation?		
8 EXAMINATION					
9 QUESTIONS BY MR. JAMES	5		21		
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1 EXHIBIT INDEX			1 MICHELE L. COTE, PH.D., M.P.H.		
2			2 the witness herein, having been first duly sworn to		
3 Exhibit Description Page			3 tell the truth, the whole truth, and nothing but the		
4 Exhibit 1 Notice of Deposition	8		4 truth, was examined and testified as follows:		
5 Exhibit 2 Dr. Cote Expert Report	9		5 EXAMINATION,		
6 Exhibit 3 Dr. Cote Invoices	10		6 QUESTIONS BY MR. JAMES:		
7 Exhibit 4 Association of Inflammation-Related	59		7 Q Good morning, Doctor.		
8 Exposures and Ovarian Cancer Survival			8 A Good morning.		
9 In a Multi-State Study of Black women			9 Q I'm Scott James. I'm counsel for the defendant.		
10 Exhibit 5 Ovarian Cancer Treated At Karmanos	77		10 I will take your deposition today.		
11 Exhibit 6 Ovarian Cancer Facts and Prevention	79		11 Can you state your full name for the record?		
12 Exhibit 7 Karmanos Hope, The Truth About Talc	83		12 A Michele Lynn Cote.		
13 Exhibit 8 AACR Ovarian Cancer	87		13 Q Where are you employed?		
14 Exhibit 9 Ovarian, Fallopian Tube, and Primary	91		14 A Indiana University, Indianapolis.		
15 Peritoneal Cancers Prevention - Health			15 Q Do you have any other current employers?		
16 Professional Version			16 A No.		
17 Exhibit 10 WCRFI Ovarian Cancer	99		17 Q Any additional employers or institutions from		
18 Exhibit 11 Facts About Talc	155		18 which you currently earn income?		
19 Exhibit 12 BJC Analgesic Medication Use and Risk	165		19 A No. I mean, we do have some grant review type		
20 of Epithelial Ovarian Cancer in African			20 work we do for the federal government on occasion.		
21 Women			21 That is all.		
22 Exhibit 13 The Transport of Carbon Particles in the			22 Q Do you earn income from Komen?		
23 Human Female Reproductive Tract	182		23 A No.		
24 Exhibit 14 Migration of Talc From the Perineum to	192		24 Q Do you operate any separate consulting business		
25 Multiple Pelvic Organ Sites			25 for your expert work?		
26 Exhibit 15 Analytic Comparison of Talc in	197				
27 Commercially Available Baby Powder and					
28 in Pelvic Tissues Resected From Ovarian					
29 Carcinoma Patients					
30 Exhibit 16 Does Long-Term Talc Exposure Have a	201				
31 Carcinogenic Effect on the Female Genital					
32 System of Rats?					

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1 A No.	1 correct?
2 Q Have you disclosed to your employer that you are	2 A Yes.
3 doing litigation work?	3 Q You are providing your testimony today just as if
4 A Yes.	4 you were in front of a judge or jury.
5 Q Do they have policies that require such a	5 Do you understand that?
6 disclosure?	6 A Yes.
7 A No.	7 Q Have you ever done any prior work as an expert in
8 Q Do they know the subject matter of your litigation	8 any litigation?
9 work?	9 A No.
10 A Yes.	10 (EXHIBIT NUMBER 1 WAS MARKED FOR
11 Q You understand today that we are here to take your	11 IDENTIFICATION.)
12 deposition in the talc MDL and also in the talc	12 Q I'm going to hand you Exhibit Number 1, a copy of
13 New Jersey state court litigation?	13 the deposition notice. Okay?
14 A Yes.	14 A Okay.
15 Q Have you been disclosed as an expert in any other	15 Q Okay. And, Dr. Cote, have you seen this document
16 talc litigation?	16 before?
17 A No.	17 A Yes, I have.
18 Q When were you first contacted about serving as an	18 Q Turn to Page 3.
19 expert in the talc litigation?	19 A Yes.
20 A I believe it was January of last year. So	20 Q Do you see there is a Schedule A?
21 January 2023.	21 A I do.
22 Q Okay. Who first contacted you?	22 Q Then below that it says Documents To Be Produced.
23 A Ms. Parfitt.	23 Do you see that?
24 Q When did you agree to serve as an expert in the	24 A Yes.
25 talc litigation?	25 Q There are several pages with document requests.
Page 7	
1 A It was at some point I think later that summer or	1 Do you understand that?
2 maybe even early, like, early September. Fairly	2 A Yes, I see that.
3 recently.	3 Q Did you review this list of document requests?
4 Q And we are discussing 2023 still?	4 A I did at the time I received this.
5 A Yes.	5 Q Did you bring any documents with you today that
6 Q Did you have any prior work or relationship with	6 have not yet been produced to me?
7 plaintiff's counsel?	7 A No.
8 A No.	8 Q I understand that in this case you have produced
9 Q Is this your first deposition?	9 an expert report.
10 A Yes.	10 A Yes.
11 Q In your lifetime?	11 Q I will mark that as Exhibit Number 2.
12 A Yes.	12 (EXHIBIT NUMBER 2 WAS MARKED FOR
13 Q Have you ever given any type of deposition or	13 IDENTIFICATION.)
14 sworn testimony in any type of proceeding before?	14 Q Do you have a working copy of the expert report
15 A No.	15 that you plan to use to work with?
16 Q Today I will ask you questions. I ask that you	16 A I do.
17 answer me verbally rather than nods or shakes.	17 Q I have clean copies if you would like one.
18 A I will do my best, yes.	18 A Okay.
19 Q If you are tired or need a break, let me know.	19 Q I will mark your expert report as
20 I'm happy to break at your convenience.	20 Exhibit Number 2.
21 A Yes.	21 MR. JAMES: Counsel, I presume you have
22 Q It will be a full day. I understand we will take	22 copies as well?
23 a lunch break as well.	23 MS. PARFITT: Yes.
24 A Yes.	24 Q You have produced a set of invoices in this case?
25 Q You understand today you are under oath, is that	25 A I believe Michelle has those.

<p style="text-align: right;">Page 10</p> <p>1 Q I will mark the collection of invoices as Exhibit 2 Number 3.</p> <p>3 (EXHIBIT NUMBER 3 WAS MARKED FOR 4 IDENTIFICATION.)</p> <p>5 Q Are there any other responsive materials to the 6 Schedule A that you brought with you today other 7 than the report and the invoices?</p> <p>8 A No.</p> <p>9 Q I see that you have in front of you a fairly 10 substantial binder, correct?</p> <p>11 A Three of them, yes.</p> <p>12 Q Fair enough. Can you in a very brief fashion 13 explain to me what are in those binders?</p> <p>14 A My expert report. My C.V. Then the literature 15 that was all cited in my expert report.</p> <p>16 Q Okay. Do the binders contain the literature cited 17 and also the additional materials considered, or 18 just the literature cited?</p> <p>19 A Just the literature cited.</p> <p>20 MS. PARFITT: For the record, we provided 21 counsel with a drop box of reference materials. 22 She should have access to that.</p> <p>23 MR. JAMES: Understood.</p> <p>24 Q It looks to me like your binders, that at least 25 some of the materials may be work copies, is that</p>	<p style="text-align: right;">Page 12</p> <p>1 Q Let's start with --</p> <p>2 A Let's look and see.</p> <p>3 Q There should be one that is multiple pages.</p> <p>4 A So the top one dated 1/8/2024?</p> <p>5 MS. PARFITT: 11/2/23.</p> <p>6 Q Do you have one dated 11/2?</p> <p>7 A Yes. One of these is the incorrect cover sheet 8 perhaps.</p> <p>9 Q Okay. Focusing on the one that has a cover sheet 10 of 11/2, do you see that?</p> <p>11 A Yes, I do.</p> <p>12 Q Do you see that that invoice, or set of invoices 13 has work for March, September, and October, 14 correct?</p> <p>15 A Right.</p> <p>16 Q The second invoice that was produced to us has a 17 cover sheet dated 1/8/2024.</p> <p>18 MS. PARFITT: There are two marked 19 1/8/2024. They are different invoices.</p> <p>20 Q One of those invoices is for work in 21 November 2023, correct?</p> <p>22 A Yes. That is correct.</p> <p>23 Q And then the second invoice that has a cover sheet 24 of 1/8 is for work in December of 2023, is that 25 correct?</p>
<p style="text-align: right;">Page 11</p> <p>1 fair?</p> <p>2 A Yes.</p> <p>3 Q You have marked up, I see, the report in front of 4 you, correct?</p> <p>5 A Sure.</p> <p>6 Q Do any of the materials, the report that you have 7 in front of you in the binders, do they have 8 substantive notes that include additional 9 opinions?</p> <p>10 A No.</p> <p>11 Q Is it all just highlighting?</p> <p>12 A Tabs and highlighting, yes.</p> <p>13 Q Let's look briefly at your invoices.</p> <p>14 Do you have a copy of those in front of you?</p> <p>15 A I do not.</p> <p>16 Q I have a copy.</p> <p>17 A Okay. Thank you.</p> <p>18 Q You have produced to us in this case three 19 invoices.</p> <p>20 You have produced an invoice to us for work 21 for March, September, and October 2023.</p> <p>22 Do you see that first invoice?</p> <p>23 A I have that.</p> <p>24 Q It should be the top one.</p> <p>25 A I think I have a double copy here.</p>	<p style="text-align: right;">Page 13</p> <p>1 A Yes, that is correct.</p> <p>2 Q Okay. Are these all of the invoices that you 3 have invoiced to date for your work in this 4 litigation?</p> <p>5 A I believe so.</p> <p>6 Q I have calculated the invoices that you have 7 produced to us.</p> <p>8 Thus far the invoices that you have produced 9 to us reflect that you have invoiced for 116.5 10 hours of work in this litigation.</p> <p>11 Does that sound accurate?</p> <p>12 A Yes, that sounds correct.</p> <p>13 Q You have invoiced for us fees totaling \$46,600.</p> <p>14 Does that sound correct?</p> <p>15 A That sounds correct, yes.</p> <p>16 Q Have you done work since your December invoices in 17 this litigation?</p> <p>18 A Yes. I have been preparing for this.</p> <p>19 Q Do you have an approximate or estimate of how much 20 time you have spent since your last invoice 21 working in this litigation?</p> <p>22 A Maybe twenty hours not counting today.</p> <p>23 Q And at some point you plan to invoice counsel for 24 that time, correct?</p> <p>25 A After today, yes.</p>

<p>1 MR. JAMES: Counsel, we would request that 2 you produce the supplemental invoice when it's 3 available.</p> <p>4 MS. PARFITT: Of course.</p> <p>5 Q I see in the top invoice the cover sheet of 11/2. 6 Can you open that one for me, the 11/2 cover 7 sheet?</p> <p>8 A Yes.</p> <p>9 Q I see that the first entry that is invoiced is 10 from March 15, do you see that?</p> <p>11 A Yes, I do.</p> <p>12 Q That says Introductory Meeting. 13 Do you see that?</p> <p>14 A Uh-huh.</p> <p>15 Q Is that yes?</p> <p>16 A Yes. I'm sorry.</p> <p>17 Q No worries. Is that the first call that you had 18 with counsel about working on this litigation?</p> <p>19 A I actually believe I spoke briefly with Michelle 20 sometime -- I received an email, like, the end of 21 January. We spoke briefly over the phone.</p> <p>22 Then we have -- I thought about it some. We 23 set up a call for March. So, yes.</p> <p>24 Q And then I see that on 3/23 you invoiced for 120 25 minutes of first literature review.</p>	<p>Page 14</p> <p>1 Q Over the course of your work in this litigation 2 have you had meetings with anyone other than 3 Ms. Parfitt and Ms. O'Dell?</p> <p>4 A Yes. Chris has been on some of those calls.</p> <p>5 Patrick, who is on the phone today, has been 6 on some of those calls. I really think that is it 7 that I can recall.</p> <p>8 Q Just for purposes of the record, you are referring 9 to Mr. Tisi and Mr. Lyons, correct?</p> <p>10 A Yes.</p> <p>11 Q Is the time that you have spent since December, 12 has that been dedicated to preparing for today's 13 deposition?</p> <p>14 A Yes.</p> <p>15 Q Have you done any additional review of new 16 materials since the December time period?</p> <p>17 A Some things as they have come in, yes.</p> <p>18 Q I see your expert report is dated November 15, 19 correct?</p> <p>20 A Correct.</p> <p>21 Q Are there any additional materials that you are 22 relying on for the opinions that you intend to 23 offer in this litigation that are not captured in 24 the report?</p> <p>25 A No, not for the overall opinion.</p>
<p>1 Do you see that?</p> <p>2 A Yes.</p> <p>3 Q And then on 3/27 you have invoiced for a review 4 history call, is that correct?</p> <p>5 A Yes, that is correct.</p> <p>6 Q At the time on 3/27 had you reached the opinion 7 that talc as a perineal talc use is a general 8 cause of ovarian cancer?</p> <p>9 A I had not, no.</p> <p>10 Q When did you reach that opinion?</p> <p>11 A At some point later this fall during my broader 12 review of multiple lines of evidence. At this 13 point in March I had really just focused on the 14 epidemiological literature.</p> <p>15 I felt confident that there would be enough 16 there for me to come to an opinion. So I agreed 17 to kind of take on this work.</p> <p>18 Q Okay. That first call was with Ms. Parfitt, 19 correct?</p> <p>20 A I believe so. I believe Leigh may have been on 21 that call as well.</p> <p>22 Q Ms. O'Dell?</p> <p>23 A Yes, Ms. O'Dell.</p> <p>24 Q Was anyone else on that call?</p> <p>25 A Not to my recollection, no.</p>	<p>Page 15</p> <p>1 Q When you say not for the overall opinion, what do 2 you mean?</p> <p>3 A There is additional data that has come forth since 4 that time or additional announcements that I've 5 considered, but they are not, they didn't inform 6 or change or alter my final opinions in the 7 report.</p> <p>8 Q Okay. Where would I look to find out what 9 additional materials have informed your overall 10 opinions since the report?</p> <p>11 A I don't know if it has informed my overall 12 opinion. It has just been out there in the media 13 that the EPA banned the import of asbestos. You 14 know, that is one example.</p> <p>15 That was, you know, broadly in the media as 16 well as, you know, on the internet.</p> <p>17 Q Any other examples that come to mind as you sit 18 here today?</p> <p>19 A That is the most recent one.</p> <p>20 Q Is there any scientific literature that predated 21 your November 15 report that you have since 22 reviewed that you intend to rely on for the 23 opinions in this case?</p> <p>24 A That is not included in here?</p> <p>25 Q Correct.</p>

<p style="text-align: right;">Page 18</p> <p>1 A No.</p> <p>2 Q I understand you are charging \$400 an hour for</p> <p>3 your time in this litigation?</p> <p>4 A Yes.</p> <p>5 Q Is that the rate for all of the activity that you</p> <p>6 have done in this litigation whether it be review</p> <p>7 or testimony?</p> <p>8 A Yes.</p> <p>9 Q Do you know any experts that the plaintiffs have</p> <p>10 retained to work on this litigation?</p> <p>11 A Yes. I know Trish Moorman. Trisha Moorman.</p> <p>12 Q Have you discussed this litigation with</p> <p>13 Dr. Moorman?</p> <p>14 A No.</p> <p>15 Q How are you aware that she is an expert for the</p> <p>16 plaintiffs in this litigation?</p> <p>17 A When Michelle contacted me, she, I asked how she</p> <p>18 got my name and it was through Dr. Moorman.</p> <p>19 Q Do you know Dr. Moorman professionally or</p> <p>20 personally or both?</p> <p>21 A Professionally.</p> <p>22 Q Have you co-authored papers with Dr. Moorman?</p> <p>23 A Yes, we have.</p> <p>24 Q Was Dr. Moorman on the Schildkraut 2016 paper?</p> <p>25 A She was indeed. She was the last author.</p>	<p style="text-align: right;">Page 20</p> <p>1 Trisha Moorman and Anne McTiernan.</p> <p>2 Q Have you reviewed any expert reports from any</p> <p>3 epidemiologists that are retained by the</p> <p>4 defendants in this litigation?</p> <p>5 A No, I don't believe so.</p> <p>6 Q Have you reviewed any expert reports for any</p> <p>7 experts retained by the defendants in this</p> <p>8 litigation?</p> <p>9 A No.</p> <p>10 MS. PARFITT: Objection.</p> <p>11 Q Have you reviewed any recent reports, anything</p> <p>12 more recent from plaintiff expert retained</p> <p>13 epidemiologists other than the McTiernan and</p> <p>14 Moorman 2017 reports that you referred to?</p> <p>15 A I did briefly review Dr. Moorman's deposition from</p> <p>16 a couple weeks ago.</p> <p>17 Q You are referring to her deposition?</p> <p>18 A Yes.</p> <p>19 Q Have you reviewed any other deposition testimony</p> <p>20 of plaintiffs' retained experts in this</p> <p>21 litigation?</p> <p>22 A No.</p> <p>23 Q Why did you review Dr. Moorman's deposition</p> <p>24 testimony?</p> <p>25 A As I stated, I have never done this before. I</p>
<p style="text-align: right;">Page 19</p> <p>1 Q Do you know anything else about why Dr. Moorman</p> <p>2 recommended you?</p> <p>3 MS. PARFITT: Objection.</p> <p>4 A No.</p> <p>5 Q Do you know any other experts that are working for</p> <p>6 the plaintiffs in the talc litigation besides</p> <p>7 Dr. Moorman?</p> <p>8 A Not personally, no.</p> <p>9 Q Do you know the identity of any other experts who</p> <p>10 are working for the plaintiffs in the talc</p> <p>11 litigation?</p> <p>12 A I have heard names.</p> <p>13 Q Who have you heard?</p> <p>14 A This will be a memory test. Anne McTiernan. Sunil,</p> <p>15 I don't recall the last name.</p> <p>16 MS. PARFITT: Singh.</p> <p>17 A Singh. Yes. Harlow. Rothman. That's all my</p> <p>18 brain is coming up with this morning.</p> <p>19 Q Okay. Have you ever communicated with any of the</p> <p>20 plaintiff experts in this litigation about talc</p> <p>21 and ovarian cancer?</p> <p>22 A No.</p> <p>23 Q Have you reviewed the expert reports of any other</p> <p>24 plaintiff experts in this litigation?</p> <p>25 A I did review a report from, I think, 2017 of</p>	<p style="text-align: right;">Page 21</p> <p>1 just kind of wanted to get an idea of how the day</p> <p>2 would go.</p> <p>3 Q Do you know Ghassan Saed, S-A-E-D?</p> <p>4 A No, I do not.</p> <p>5 Q Do you know Nicole Fletcher?</p> <p>6 A No.</p> <p>7 Q Amy Harper, do you know her?</p> <p>8 A No.</p> <p>9 Q Have you ever heard of those names?</p> <p>10 A Yes. They are in my materials.</p> <p>11 Q Okay. Understood. Before you reviewed their</p> <p>12 materials for your work in this litigation had you</p> <p>13 ever heard of them?</p> <p>14 A No.</p> <p>15 Q Before you reviewed their literature in the</p> <p>16 context of this litigation had you ever worked</p> <p>17 with them?</p> <p>18 A No, I had not.</p> <p>19 Q Do you understand that Saed is at Wayne State?</p> <p>20 A I do, yes.</p> <p>21 Q And when you were at Wayne State did you have any</p> <p>22 interactions with him?</p> <p>23 A Not to my recollection, no.</p> <p>24 Q When you were at Wayne State or at Karmanos did</p> <p>25 you have any interactions with Saed, Harper, or</p>

<p style="text-align: right;">Page 22</p> <p>1 Fletcher?</p> <p>2 A No.</p> <p>3 Q Did you ever collaborate with any of them on any</p> <p>4 work?</p> <p>5 A No.</p> <p>6 Q Did you ever review any of their studies or</p> <p>7 literature before -- let me start over.</p> <p>8 Did you ever review any of their literature</p> <p>9 or studies before being retained in this</p> <p>10 litigation?</p> <p>11 A No.</p> <p>12 Q Do you understand that Dr. Saed is a paid</p> <p>13 plaintiffs' expert in this litigation?</p> <p>14 A I do.</p> <p>15 Q Do you know how his studies were funded?</p> <p>16 A I do not.</p> <p>17 Q When I refer to his studies, I'm referring to any</p> <p>18 studies on which he is a co-author.</p> <p>19 Do you understand that?</p> <p>20 A I do understand that.</p> <p>21 Q And do you understand he has co-authored with</p> <p>22 Fletcher?</p> <p>23 A Yes.</p> <p>24 Q Fletcher is one of the literature references in</p> <p>25 your report, correct?</p>	<p style="text-align: right;">Page 24</p> <p>1 A At some point in time I'm open to reviewing</p> <p>2 literature from anywhere.</p> <p>3 Q Are you aware that the comments to those</p> <p>4 publications contain serious scientific concerns</p> <p>5 about the validity of those studies?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 A No.</p> <p>8 Q Do you know how many journals have rejected the</p> <p>9 articles published by Saed, Fletcher, or Harper?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 A No.</p> <p>12 Q Would you like to know that?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 A No.</p> <p>15 Q And would peer reviewed comments on those</p> <p>16 publications impact or inform your opinions in</p> <p>17 this litigation?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 A No.</p> <p>20 Q Why not?</p> <p>21 A During the review process, speaking as somebody</p> <p>22 who was co-authored over 150 different papers,</p> <p>23 when we send it to a journal, send it meaning our</p> <p>24 final manuscript to a journal, they assign</p> <p>25 reviewers.</p>
<p style="text-align: right;">Page 23</p> <p>1 A Correct.</p> <p>2 Q Do you know if his studies were funded by the</p> <p>3 plaintiffs' bar or through his work in the</p> <p>4 plaintiffs' litigation?</p> <p>5 MS. PARFITT: Objection.</p> <p>6 A I do not know. I believe that he lists his work</p> <p>7 as a consultant in the talc trials as a conflict</p> <p>8 of interest or additional information on the</p> <p>9 manuscript.</p> <p>10 But that is the extent about how he was</p> <p>11 funded that I know.</p> <p>12 Q All you know is what is disclosed in the conflict</p> <p>13 of interest, correct?</p> <p>14 A Yes.</p> <p>15 Q Have you ever reviewed any peer review comments</p> <p>16 associated with any studies published by Saed,</p> <p>17 Fletcher, or Harper?</p> <p>18 A No.</p> <p>19 Q Are you aware that peer reviewed comments for</p> <p>20 those studies have been published in this</p> <p>21 litigation?</p> <p>22 A No.</p> <p>23 Q Would you like to review the peer reviewed</p> <p>24 comments to those studies?</p> <p>25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 25</p> <p>1 Oftentimes they -- most of the time the</p> <p>2 reviewers are unknown to us. We don't have an</p> <p>3 open policy of disclosing. It is not at all</p> <p>4 unusual to get reviewer comments back even if the</p> <p>5 journal accepts.</p> <p>6 So you have no way of really vetting who is</p> <p>7 reviewing your work. You have to kind of trust</p> <p>8 that the editor is making an informed decision</p> <p>9 that the people who are reviewing the manuscript</p> <p>10 have the appropriate scientific expertise.</p> <p>11 And that is a pretty big assumption. So I</p> <p>12 would assume that because a journal eventually</p> <p>13 published it, that the editorial board was</p> <p>14 satisfied with the response to the reviewers'</p> <p>15 comments, that if there were any glaring errors or</p> <p>16 issues with the scientific methodology that they</p> <p>17 would have been resolved, or else the journal</p> <p>18 would not have published that manuscript.</p> <p>19 They are experts in that field. I'm not an</p> <p>20 expert in the type of work that they were doing.</p> <p>21 So it would not be particularly useful for me to</p> <p>22 review the comments.</p> <p>23 Q Are you an expert in the in vitro work that Saed</p> <p>24 does?</p> <p>25 A No, I'm not.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q If those comments identified scientific flaws in 2 the studies would you consider the comments for 3 that purpose?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 A As I stated earlier, I would assume that those 6 issues were resolved adequately in order for the 7 paper to be peer reviewed published.</p> <p>8 Q Have you ever reviewed any of the litigation 9 reports authored by Dr. Saed in this talc 10 litigation?</p> <p>11 A No, I've not.</p> <p>12 Q Do you recognize that epithelial ovarian cancer 13 includes multiple subtypes?</p> <p>14 A I do, yes.</p> <p>15 Q Do you agree that the "Histologic subtypes are 16 differentiated based on the cell origin, molecular 17 alterations, and clinical behavior." Is that 18 Correct?</p> <p>19 A Generally speaking, yes.</p> <p>20 Q I believe I was quoting from your report.</p> <p>21 A Yes.</p> <p>22 Q For example, in your report you note that 23 endometrioid and clear cell tumors can arise from 24 endometriosis, correct?</p> <p>25 A Yes, that is in my report.</p>	<p style="text-align: right;">Page 28</p> <p>1 is there are distinct subtypes of ovarian cancer, 2 epithelial ovarian cancer.</p> <p>3 Q Is your expert opinion that perineal talc use is 4 associated with all subtypes of EOC or only some 5 subtypes of EOC?</p> <p>6 A As I was asked to review, it would be all subtypes 7 of EOC.</p> <p>8 Q And so your testimony is that perineal talc use is 9 associated with high grade serous, low grade 10 serous, endometrioid, clear cell, mucinous, and 11 borderline ovarian cancer?</p> <p>12 A Yes, I would. There's varying strength of 13 evidence, but I only considered it as a whole. 14 And given that high grade serous is the most 15 common form of EOC, most of the findings are 16 driven by the subtype.</p> <p>17 Q Did you undertake a histopathology specific 18 analysis of the subtypes and the associations 19 between talc and ovarian cancer?</p> <p>20 A No, I did not.</p> <p>21 Q Is it conceivable to you that an agent like 22 perineal talc can cause the diverse subtypes of 23 epithelial ovarian cancer?</p> <p>24 A I guess I need clarification of that question. 25 Are you talking about the differentiations</p>
<p style="text-align: right;">Page 27</p> <p>1 Q You also note in your report important differences 2 on cell origin, molecular alterations, clinical 3 behavior for all of the subtypes, including 4 endometrioid, clear cell, high grade serous, low 5 grade serous, mucinous, correct?</p> <p>6 A Correct.</p> <p>7 Q Do you agree that EOC, or epithelial ovarian 8 cancer, is composed of multiple distinct cancers 9 each with different clinical presentation, 10 different histopathology, different molecular 11 pathogenesis, different disease course and 12 different responses to various types of therapy?</p> <p>13 MS. PARFITT: Objection. Compound.</p> <p>14 A I would agree that we are still exploring some of 15 the molecular characteristics of these different 16 subtypes and that it is extraordinarily likely 17 that that will lead to differences in response to 18 treatment and some of the other factors that you 19 listed, yes.</p> <p>20 Q Would you agree that the subtypes of EOC that fall 21 under the umbrella are actually distinct cancers?</p> <p>22 A I would state that I am not a pathologist for the 23 record, but I do collaborate routinely with 24 pathologists.</p> <p>25 And so my understanding as an epidemiologist</p>	<p style="text-align: right;">Page 29</p> <p>1 that talc could drive the differentiation of these 2 different subtypes?</p> <p>3 Q Yeah. I can try to rephrase.</p> <p>4 A Okay.</p> <p>5 Q Is it plausible to you, is it biologically 6 plausible to you that a particle like talc could 7 cause all of these distinct types of cancer?</p> <p>8 A Well, we are talking about two different things 9 here. I mean, biological plausibility is part of 10 considering causation.</p> <p>11 So that is two different things. Do 12 different subtypes emerge from different 13 backgrounds, and what I mean by that is the tissue 14 background, kind of the microenvironment, the 15 surrounding tissue, yes. That is possibly how 16 different subtypes are differentiated.</p> <p>17 Again, I'm not a pathologist. I really 18 considered this just EOC as a whole.</p> <p>19 Q Is it biologically plausible in your mind that 20 talc causes endometriosis-related ovarian cancer?</p> <p>21 A I will restate the question.</p> <p>22 Is it biologically plausible in my mind that 23 talc causes endometriosis-associated ovarian 24 cancer?</p> <p>25 Q That's fair.</p>

<p style="text-align: right;">Page 30</p> <p>1 A Again, I'm struggling with the word causation here 2 because we are talking about is it biologically 3 plausible. I think that there was a good 4 meta-analysis, and I'm going to refer to exactly 5 which one it was, that focused on -- it's the most 6 recent one. Phung from 2022. 7 And that was kind of the point of their 8 meta-analysis, was to stratify by women who had 9 reported endometriosis and those who reported no 10 endometriosis and they found evidence that talc 11 was associated with both groups of women. 12 And so, you know, causal, that is one paper. 13 I am hesitating to use the word causal 14 because I didn't look at causation specifically 15 for endometriosis, related or not. 16 Q You did look at plausibility as part of your 17 Bradford Hill analysis, correct? 18 A Yes. 19 Q You did talk about the different histotypes in 20 your report, correct? 21 A Yes. 22 Q You specifically highlighted endometriosis and 23 endometroid ovarian cancer in your report, 24 correct? 25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 32</p> <p>1 supports that. Talc has also been shown to be 2 potentially among users a chronic inflammatory, 3 can promote a chronic inflammatory state. But 4 they are, indeed, two distinct things. 5 Q The type of inflammation you are referring to with 6 endometriosis is totally different than the type 7 of inflammation that talc causes, correct? 8 MS. PARFITT: Object to form. 9 A That I don't know. I didn't study that question 10 in particular. What are the different types of 11 immune cells involved in each, that I don't know. 12 That would be for an immunologist. 13 Q Do you know if endometriosis-related inflammation 14 is hormonally driven? 15 Are you aware of that? 16 A I've seen some, some research that suggests that 17 particularly after, you know, for postmenopausal 18 women, oftentimes their symptoms of endometriosis 19 are less. 20 So that would suggest that it is hormonally 21 driven, but that is the extent of my knowledge. 22 Q Do you agree with me that the type of inflammation 23 or biological reaction associated with 24 endometriosis is dramatically different than what 25 you are alleging happens with the talc, is that</p>
<p style="text-align: right;">Page 31</p> <p>1 A Yes. I didn't specifically highlight those, but I 2 talked about them because they are in the 3 literature. And, you know, as I have noted in 4 this meta-analysis by Phung, that has been, the 5 endometriosis association has been studied 6 previously. And so it was apparent in the 7 literature. 8 Q But you didn't just talk about endometriosis and 9 endometroid ovarian cancer from an epidemiologic 10 perspective. You also talked about it from a 11 plausibility perspective and a mechanism 12 perspective, correct? 13 MS. PARFITT: Objection. 14 A I'm going to have to review what I said about my 15 biologic plausibility before I answer that. 16 Q Let me ask you a different question then. 17 A Okay. 18 Q Do you believe that because endometriosis can be 19 referred to as an inflammatory condition that that 20 somehow supports your opinion that talc can cause 21 ovarian cancer? 22 MS. PARFITT: Objection. Form. 23 You can answer. 24 A Because endometriosis is an inflammatory 25 condition, which, yes, I believe the literature</p>	<p style="text-align: right;">Page 33</p> <p>1 correct? 2 MS. PARFITT: Objection. Form. 3 MS. FNKEN: Objection. 4 A I guess I would first ask what does dramatically 5 different mean? 6 Q What does dramatically different mean to you? 7 Like, widely different? A big difference? 8 You can use whatever term you want. 9 MS. PARFITT: Object to the question. 10 You may answer. 11 A In my mind there are multiple pathways that get to 12 the end point of inflammation and endometriosis 13 may be one. Talc may be one. Chronic, you know, 14 obesity and body weight may be another. 15 Does the end state and the result of that 16 inflammation differ? That is something that I 17 don't know. And, again, what that would really 18 take to best dissect your question and to answer 19 it would be, like, an actual study of the immune 20 cells, you know, what is present in that tissue, 21 looking at different ratios of different types of 22 immune cells. 23 I don't have those data. I don't know if 24 those data even exist. 25 Q Do you have the expertise to comment on whether</p>

<p style="text-align: right;">Page 34</p> <p>1 endometriosis related inflammation is in any way 2 relevant to talc associated inflammation? 3 MS. PARFITT: Objection. Form. 4 A Do I have the expertise to determine whether 5 there's an association between 6 endometriosis-related or if they are equivocal? 7 Q No. I'm asking more of a question about 8 biological mechanism which is covered in your 9 report, correct? 10 A Correct. 11 Q Do you have the expertise to make the statements 12 that because there is endometriosis-related 13 inflammation that that somehow persuades you that 14 talc may be causing ovarian cancer? 15 MS. PARFITT: Objection. 16 A As I mentioned -- 17 MS. FNKEN: Objection. 18 A Those are two very distinct things in my mind. 19 Q And by those two things, you mean talc and 20 endometriosis are distinct? 21 A Correct. They are two distinct things. 22 Q Do you believe the cohort data from the talc 23 ovarian cancer studies demonstrates a histologic 24 specific association? 25 A That is a broad question. I would say overall I</p>	<p style="text-align: right;">Page 36</p> <p>1 necessarily all over the map. 2 As I said, most of them are still positive. 3 I think that there is a very good discussion in 4 Cramer, the latest literature review and 5 meta-analysis from 2016 that discusses recall bias 6 and the fact that you do see, I think in 7 particular for mucinous, you don't see as positive 8 of an association. You know, the odds ratios or 9 the meta odds ratio is lower than for some of the 10 other subtypes. 11 And so he uses that as rationale, which I 12 believe that is evidence suggesting that recall 13 bias is not a significant issue in the studies. 14 Q There you are reverting to the point that is 15 contradicting the point that you just made a few 16 minutes ago. 17 There you are reverting to the point that 18 there is subtype differences, which might be 19 proving that the association is relevant for some 20 subtypes and not for others. 21 You are using that point to sort of discount 22 recall bias, right? 23 MS. PARFITT: Objection. Form. Misstates 24 her testimony. 25 A No, I'm talking about two different things. You</p>
<p style="text-align: right;">Page 35</p> <p>1 don't believe any of the cohort data have 2 sufficient power to look at subtypes. 3 Q Are you aware that the case control studies on 4 talc and ovarian cancer show varying results for 5 varying subtypes of ovarian cancer? 6 MS. PARFITT: Objection. Form. 7 A There are certain studies that have been 8 adequately powered, and these are case controlled 9 studies, to look at different subtypes. 10 And depending on the study population, there 11 has been some variation in the point estimates 12 associated with talc. 13 Most of them are still positive, that there 14 is a positive association between talc use and 15 ovarian cancer. 16 Q If the studies on subtype are all over the map on 17 associations with subtypes and if there is varying 18 results, doesn't that suggest to you that there's 19 recall bias in play in these studies? 20 MS. PARFITT: Objection. Form. 21 MS. FNKEN: Objection. 22 MR. JAMES: And we can agree that one 23 objection is good for you all if you would like. 24 MS. PARFITT: Thank you. 25 A I would not classify the histologic types as being</p>	<p style="text-align: right;">Page 37</p> <p>1 are asking me specifically about recall bias and 2 subtypes. And I'm saying that, you know, there's 3 at least some documentation and some suggestion 4 through that Cramer 2016 paper, also I believe in 5 one of his earlier papers he does a similar 6 analysis, his paper from 1999, but it's two 7 different things. 8 You know, one is a pathway of the biological 9 plausibility of differences by subtype. This one 10 is also talking about talc and recall bias. It's 11 not comparing apples to apples in my mind. 12 Q Cramer is using the fact that in 2016 his study 13 does not show a mucinous association to say aha! 14 we can tell that there is not recall bias because 15 the association is histologically specific. 16 That is what he is doing, correct? 17 MS. PARFITT: Objection. 18 Q Yes or no? 19 A That is one piece of evidence. 20 Q But you just testified that in your mind you are 21 not offering an opinion that there are 22 histological differences with the association 23 between talc and ovarian cancer, correct? 24 MS. PARFITT: Objection. Misstates her 25 testimony.</p>

<p style="text-align: right;">Page 38</p> <p>1 A Can you repeat that?</p> <p>2 Q Sure. Your opinion here today is that talc is 3 associated with all subtypes of ovarian cancer, 4 correct?</p> <p>5 A My opinion is that talc is associated with EOC. I 6 did not do individual analyses by histologic 7 subtype.</p> <p>8 So looking specifically and saying it's 9 associated with this one, it's not associated with 10 that one, that is not part of my expert report.</p> <p>11 What, again, what Cramer, what Cramer puts 12 together is based on his data of over 2,000 cases 13 and roughly around the same number of controls. 14 And that is part of the argument as to why we 15 don't think recall bias is a significant issue in 16 these case control studies.</p> <p>17 Q That is an argument you are relying on?</p> <p>18 A That is part of it. But, you know, the argument 19 that I'm most comfortable with is actually from 20 the paper that I co-authored in 2016.</p> <p>21 It's the Schildkraut paper, where it's the 22 only case control study that collected these data 23 since the time of litigation. So all of these 24 other case control studies, these almost, I don't 25 know, thirty some studies, we collected these data</p>	<p style="text-align: right;">Page 40</p> <p>1 A I do.</p> <p>2 MS. PARFITT: Let her finish.</p> <p>3 Q That was the question. That was the question.</p> <p>4 We will talk about Schildkraut later today.</p> <p>5 Okay?</p> <p>6 A Okay.</p> <p>7 Q Schildkraut, in your report, you said provides 8 some level of evidence of recall bias, is that 9 correct?</p> <p>10 A Correct.</p> <p>11 Q Do you believe that perineal talc use is 12 associated with any types of cancer other than 13 epithelial ovarian cancer?</p> <p>14 A I did not do systematic review looking at any 15 other kinds of, you know, cancers potentially 16 associated with perineal talc, so I can't answer 17 that question conclusively.</p> <p>18 Q Sitting here today have you formed the opinion 19 that talc causes any type of cancer other than 20 epithelial ovarian cancer? Yes or no?</p> <p>21 MS. PARFITT: Objection. Asked and 22 answered.</p> <p>23 Q Do you have an opinion today?</p> <p>24 A No, I have no opinion.</p> <p>25 Q After counsel makes an objection you are permitted</p>
<p style="text-align: right;">Page 39</p> <p>1 prior to, you know, the association between talc 2 and ovarian cancer being broadly known by the 3 public. Certainly before, you know, there were 4 lawsuits and all of this in the media.</p> <p>5 So what we were able to show in the 6 Schildkraut paper, we stratified from interviews 7 prior to 2014 and after 2014. And definitely 8 there is an attenuation of the odds ratio, so that 9 there was some evidence that there was potentially 10 recall bias in the group that was interviewed 11 after 2014, which is a really small subset of 12 women in the grand scheme of things when you look 13 at all of the cases and controls.</p> <p>14 We still had evidence consistent with an 15 association between talc use and EOC in the women 16 who were interviewed prior to that time. That was 17 really in line with the increase in risk seen in 18 these other four or five decades of studies.</p> <p>19 Q So there, your testimony there was related to the 20 fact that you have other reasons to discount 21 recall bias, correct?</p> <p>22 A Correct.</p> <p>23 Q I was specifically asking about Cramer's 24 histologic point that you were making.</p> <p>25 Do you understand that?</p>	<p style="text-align: right;">Page 41</p> <p>1 to answer unless she instructs you not to answer.</p> <p>2 A I realize. Thank you.</p> <p>3 Q Are you aware that the epidemiologic literature 4 shows that there is no association between 5 perineal talc use and endometrial ovarian -- 6 endometrial cancer?</p> <p>7 I will restate it.</p> <p>8 Are you aware that literature shows that 9 there is no association between peritoneal talc 10 use and endometrial cancer?</p> <p>11 MS. PARFITT: Objection to form.</p> <p>12 A I have seen -- I have studied endometrial cancer.</p> <p>13 I have seen some data indicating no association.</p> <p>14 Q But sitting here today, you don't have an opinion 15 on it one way or the other?</p> <p>16 A Correct. Sitting here today, no opinion. I've 17 not done a systematic review of the literature.</p> <p>18 Q I saw in your C.V. that you were on the 19 Epidemiology Endometrial Cancer Consortium 20 Steering Committee, is that correct?</p> <p>21 A Correct.</p> <p>22 Q And if there was evidence to support the notion 23 that perineal talc use causes endometrial cancer, 24 you would be aware of that evidence, is that 25 correct?</p>

<p>1 MS. PARFITT: Objection.</p> <p>2 A No, not necessarily. E2C2 is what we call it.</p> <p>3 What the Epidemiology of Endometrial Cancer</p> <p>4 Consortium does is, similar to what the Ovarian</p> <p>5 Cancer Association Consortium, OCAC, does, which</p> <p>6 it brings together investigators from around the</p> <p>7 world that have case control or cohort studies.</p> <p>8 We include both case control and cohort</p> <p>9 studies. And we use this as a mechanism to pool</p> <p>10 our data and to examine the question, or to</p> <p>11 examine different questions.</p> <p>12 So in endometrial cancer, you know, we have</p> <p>13 published, I have published using the E2C2 data</p> <p>14 looking at risk factor differences between Black</p> <p>15 and White women.</p> <p>16 We have looked at all different dietary</p> <p>17 things. We are somewhat constrained by what is</p> <p>18 asked in those, in every studies' questionnaire.</p> <p>19 So, you know, we don't necessarily meet as a</p> <p>20 group even monthly. The steering committee</p> <p>21 usually only meets maybe five times a year. And</p> <p>22 really it's to examine paper proposals from, you</p> <p>23 know, investigators all over the world who want to</p> <p>24 use our data.</p> <p>25 I've not seen in my, you know, probably ten</p>	<p>Page 42</p> <p>1 A No.</p> <p>2 Q Do you believe that it is relevant to your opinion</p> <p>3 that you are offering today whether or not talc</p> <p>4 can cause endometrial cancer or cervical cancer?</p> <p>5 Do you believe it is relevant, yes or no?</p> <p>6 A No. Because there are two, those are two very</p> <p>7 different organs with very different functions.</p> <p>8 A good example is, you know, the endometrium,</p> <p>9 at least premenopausally, sheds approximately</p> <p>10 every month.</p> <p>11 The cervix, for example, is exposed to a</p> <p>12 much, kind of wider array of exposures. You know,</p> <p>13 HPV being one of them.</p> <p>14 So, again, we are looking at different organs</p> <p>15 with different functions. It is all part of the</p> <p>16 female genital tract, so it is kind of like by</p> <p>17 location, but it's different subtypes.</p> <p>18 And so when you think about specificity of</p> <p>19 the association, that is one of the considerations</p> <p>20 in Bradford Hill's analysis. Specificity, you</p> <p>21 know, kind of one exposure one disease, you know,</p> <p>22 many years ago was considered, you know, stronger</p> <p>23 evidence of a causal association. It's less so</p> <p>24 today.</p> <p>25 So if I think about other, you know, female</p>	<p>Page 44</p>
<p>1 years now of being associated with that consortium</p> <p>2 any request to look at talc. Nor do I even know</p> <p>3 how many of the different case control studies ask</p> <p>4 that question.</p> <p>5 Q So there is no professional movement to study talc</p> <p>6 in endometrial cancer, correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 A I can't say what has been going on in other</p> <p>9 circles, no.</p> <p>10 Q You are not aware of any professional focus on</p> <p>11 talc and endometrial cancer, correct?</p> <p>12 A Correct, I am not.</p> <p>13 Q Your theory or hypotheses in this case is that</p> <p>14 talc can potentially or likely migrate up the</p> <p>15 female genital tract, is that correct?</p> <p>16 A Correct.</p> <p>17 Q Is that correct?</p> <p>18 A Correct.</p> <p>19 Q Under that hypothesis, perineal talc would come</p> <p>20 into contact with the endometrium and the cervix,</p> <p>21 correct?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 A Correct.</p> <p>24 Q Yes or no, have you looked at the literature on</p> <p>25 talc and cervical cancer?</p>	<p>Page 43</p> <p>1 cancers and the association with talc for the</p> <p>2 purposes of, you know, this expert report, it</p> <p>3 would just be with respect to specificity of the</p> <p>4 exposure and the outcome.</p> <p>5 Q In your report you said that there is some</p> <p>6 evidence that the talc ovarian cancer association</p> <p>7 may be specific.</p> <p>8 A That the talc and ovarian cancer may be specific,</p> <p>9 yes.</p> <p>10 Q Do you recall putting that in your report?</p> <p>11 A Yes.</p> <p>12 Q And you cited the Wentzensen and O'Brien review</p> <p>13 article for that proposition, correct?</p> <p>14 A Yes.</p> <p>15 Q Sitting here today, just to confirm, you have not</p> <p>16 reviewed comprehensively the literature on talc</p> <p>17 and endometrial cancer and talc and cervical</p> <p>18 cancer, is that correct?</p> <p>19 A That is correct.</p> <p>20 Q You are not offering any opinions on specific</p> <p>21 causation today, correct?</p> <p>22 Do you know what that term means?</p> <p>23 A I do not.</p> <p>24 Q Okay. Let me rephrase.</p> <p>25 You are not offering an opinion today that</p>	<p>Page 45</p>

12 (Pages 42 - 45)

<p style="text-align: right;">Page 46</p> <p>1 talc specifically caused an individual's ovarian 2 cancer, correct?</p> <p>3 A Correct. I don't know anything about the 4 individuals represented in this case.</p> <p>5 Q Your opinion today is that talc can be a general 6 cause of ovarian cancer, correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 A Correct. It can be a cause of ovarian cancer.</p> <p>9 Q Okay. Have you ever reached an opinion that a 10 specific individual's ovarian cancer was caused by 11 talc?</p> <p>12 A No. I'm not familiar with individual patient 13 cases.</p> <p>14 Q Have you ever discussed with anyone whether a 15 specific individual's ovarian cancer was caused by 16 talc?</p> <p>17 A No.</p> <p>18 MS. PARFITT: Objection.</p> <p>19 Q Have you ever told a specific individual who used 20 talc that they were at an increased risk for 21 developing ovarian cancer because of their talc 22 use?</p> <p>23 A No.</p> <p>24 Q Are you aware sitting here today of any recognized 25 scientific methodology to take the body of</p>	<p style="text-align: right;">Page 48</p> <p>1 on your expertise, you world, are you aware of any 2 methodology to conclude that talc specifically 3 caused a specific individual's ovarian cancer?</p> <p>4 MS. PARFITT: Same objection.</p> <p>5 A I am unaware of any methodology, including my own, 6 that could specify that talc caused an ovarian 7 cancer in a certain individual. I'm not sure that 8 that exists.</p> <p>9 Q Do you know anything about any of the plaintiffs 10 in the MDL or the state court litigation?</p> <p>11 A No, I do not.</p> <p>12 Q Do you know anything about Ms. Rausa, Ms. Judkins, 13 Ms. Newsome, Ms. Gallardo, Ms. Converse, 14 Ms. Bondurant, Ms. Carl, or Ms. Balderrama?</p> <p>15 A No.</p> <p>16 Q Have you reviewed any of those individual's 17 medical records, pathology, radiology, 18 depositions, or discovery responses?</p> <p>19 A No.</p> <p>20 Q Do you know anything about their medical 21 histories, their subtypes of ovarian cancer, their 22 course of treatment or risk factors?</p> <p>23 A No.</p> <p>24 Q Do you know anything about their genetic or family 25 history?</p>
<p style="text-align: right;">Page 47</p> <p>1 evidence that you have reviewed and use that 2 evidence to make a conclusion that talc 3 specifically caused a specific individual's 4 ovarian cancer?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 A Can you restate that question?</p> <p>7 Q Sure. Sitting here today, are you aware of any 8 recognized scientific methodology to take the body 9 of evidence that you have used in your report and 10 conclude that talc use specifically caused a 11 specific individual's ovarian cancer?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A I'm not -- I'm still not sure even after the 14 second repeat of that question that I am 15 understanding what the point is.</p> <p>16 Am I aware -- I will try to restate it to 17 clarify it in my mind.</p> <p>18 Am I aware of any body, organization that has 19 used the methodology that I used in my report to 20 determine if a single individual, if the ovarian 21 cancer in a single individual was caused by talc, 22 is that correct?</p> <p>23 Q Let me try again.</p> <p>24 A Okay.</p> <p>25 Q Are you aware of any scientific methodology based</p>	<p style="text-align: right;">Page 49</p> <p>1 A No.</p> <p>2 Q Are you aware that multiple of your literature 3 cited references in your report are materials that 4 were authored by retained experts for the 5 plaintiffs?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 A I do.</p> <p>8 Q Can you open your report, please?</p> <p>9 A Yes.</p> <p>10 Q You have it with you. Can you please turn to your 11 literature cited page. That is on Page 41.</p> <p>12 A Yes.</p> <p>13 Q Do you know how many of your literature cited 14 references are references that are authored by 15 paid experts for the plaintiffs in this litigation 16 offhand?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 A No, I do not.</p> <p>19 Q When you cited references in your report that were 20 authored by paid experts for the plaintiffs did 21 you note that in the report?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 A I don't believe I did.</p> <p>24 Q In contrast, when you did review articles that 25 were authored by authors who were associated with</p>

<p style="text-align: right;">Page 50</p> <p>1 industry or Johnson & Johnson you did note that, 2 didn't you?</p> <p>3 MS. PARFITT: Objection.</p> <p>4 A I think sometimes I did. The difference was a lot 5 of the literature cited in the report here by 6 people who I know now are plaintiff experts or 7 that it was disclosed, it is original literature.</p> <p>8 It was in the -- I have a section. I will 9 look at it just to make sure we are talking about 10 the same thing. It was commentaries oftentimes. 11 So a lot of the things that I noted that were 12 from the defendant's experts or paid experts, were 13 based on reviews and things that did not include, 14 like, novel generated analyses, you know, based on 15 case control studies or cohort studies that they, 16 themselves, were involved in.</p> <p>17 I can give an example. Some of those are 18 on -- I'm not finding them.</p> <p>19 Q When you cited Cramer's --</p> <p>20 MS. PARFITT: She is looking for 21 something.</p> <p>22 MR. JAMES: She finished the answer.</p> <p>23 A I had not. I'm trying to find you exactly where.</p> <p>24 Q I did not ask for you to find me exactly where.</p> <p>25 MS. PARFITT: It was part of the answer.</p>	<p style="text-align: right;">Page 52</p> <p>1 A They were not paid experts for the plaintiff when 2 they started their work back in the nineties.</p> <p>3 Q My question is about the letters to the editor. 4 Do you know when those were written? Those 5 were written in 2020, correct?</p> <p>6 A Yes.</p> <p>7 Q When you cited those letters in the report did you 8 note that in the report that those were paid 9 experts for the plaintiffs?</p> <p>10 MS. PARFITT: Objection. Asked and 11 answered.</p> <p>12 Q Yes or no?</p> <p>13 A No.</p> <p>14 Q Looking at Page 43, Dr. Cote, do you see on 15 Number 34 the reference to Longo?</p> <p>16 A Yes.</p> <p>17 Q Do you understand he's a paid expert for the 18 plaintiffs?</p> <p>19 A I do.</p> <p>20 Q When you cited his material in your report did you 21 disclose that he was a paid expert for the 22 plaintiffs?</p> <p>23 MS. PARFITT: Objection.</p> <p>24 A I do not know if I did or not.</p> <p>25 Q For Number 40 do you see Crowley?</p>
<p style="text-align: right;">Page 51</p> <p>1 Q I asked you a simple question.</p> <p>2 MS. PARFITT: Scott, you may have asked a 3 very simple question. You can't --</p> <p>4 Q Which is, did you note in the report --</p> <p>5 MS. PARFITT: Scott, please. Excuse me 6 for one moment.</p> <p>7 MR. JAMES: No. You're not going to talk 8 over me. It's my deposition.</p> <p>9 MS. PARFITT: You are required under the 10 rules to allow a witness to answer responsively 11 your questions. Choose your questions carefully.</p> <p>12 You may complete your answer, Doctor.</p> <p>13 A Yes. I just wanted to note that that is on Pages 14 23 and 24 of my report.</p> <p>15 MS. PARFITT: Thank you.</p> <p>16 Q Dr. Cote, when my question calls for a yes or no, 17 that is what I'm asking for. Okay?</p> <p>18 When you cited Cramer's letter to the editor 19 and Harlow's letter to the editor, those are not 20 original pieces of literature, correct?</p> <p>21 A Correct.</p> <p>22 Q Did you note in your report when you cited those 23 letters to the editor that those were paid experts 24 for the plaintiffs?</p> <p>25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 53</p> <p>1 A Yes.</p> <p>2 Q Do you know if he is a paid expert for the 3 plaintiffs?</p> <p>4 A Yes.</p> <p>5 Q In fact, that is a litigation report that you 6 cited, correct?</p> <p>7 A I believe so.</p> <p>8 Q If you look at Page 44, Number 58?</p> <p>9 A Yes.</p> <p>10 Q When you cite the McDonald paper were you aware 11 there are paid plaintiff experts who are authors 12 of that paper?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 A I can see Cramer's name, so yes.</p> <p>15 Q Do you know that in 2019 he was a paid plaintiffs' 16 expert?</p> <p>17 A I'm aware of that.</p> <p>18 Q Do you know that Welch and McDonald and Godleski 19 are also paid plaintiff experts?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 A I do not recall those names, no.</p> <p>22 Q Turn the page. Look at Number 59.</p> <p>23 Do you see the Johnson study?</p> <p>24 A Yes.</p> <p>25 Q Okay. For Reference Number 59, do you know that</p>

<p>1 Johnson, McDonald and Godleski are paid 2 plaintiff's expert?</p> <p>3 MS. PARFITT: Objection. Asked and 4 answered.</p> <p>5 A No.</p> <p>6 MR. JAMES: Actually I had not asked about 7 Johnson yet.</p> <p>8 Q For Number 60 do you see the Godleski paper there 9 again?</p> <p>10 A Yes.</p> <p>11 Q You understand that Godleski is a paid plaintiffs' 12 expert?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 A Yes.</p> <p>15 Q Did you know that before coming here today?</p> <p>16 A I can't say specifically whether or not I did 17 unless it was disclosed on there, on this 18 publication.</p> <p>19 Q For Reference Number 64, do you see the Mandarino 20 article?</p> <p>21 A I do.</p> <p>22 Q Do you know if that is a product of a paid 23 plaintiff's expert?</p> <p>24 MS. PARFITT: Objection.</p> <p>25 A I do not.</p>	<p>Page 54</p>	<p>1 Q Mathematically just under ten percent of the 2 literature pieces that you cite, the primary 3 literature, just under ten percent is written by 4 paid plaintiffs' experts.</p> <p>5 Did you know that?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 A No, I did not know that. But it is not surprising 8 to me given that especially among epidemiologists 9 we publish in large groups.</p> <p>10 Q Does that concern you in any way, yes or no?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 A No.</p> <p>13 Q Did you note anywhere in your report all of the 14 pieces that I just mentioned were written by paid 15 plaintiffs' experts?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 A No.</p> <p>18 Q Would it have been appropriate to note that in 19 your report?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 A No. These are established scientists with, in 22 many cases, decades worth of history way before 23 the talc and ovarian cancer litigation came out 24 who have been working in this area really for the 25 entirety of their professional lives.</p>	<p>Page 56</p>
<p>1 Q For Number 66, the Fletcher paper, do you know if 2 that is the product of a paid plaintiffs' expert?</p> <p>3 MS. PARFITT: Objection. Asked and 4 answered.</p> <p>5 A Yes, we discussed that earlier.</p> <p>6 Q That is Saed, correct?</p> <p>7 A Yes.</p> <p>8 Q For Number 71, Woolen, are you aware that is a 9 product of a paid plaintiffs' expert?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 A Yes.</p> <p>12 Q Are you aware that Smith-Bindman is a paid 13 plaintiffs' expert?</p> <p>14 A Yes.</p> <p>15 MS. PARFITT: Objection.</p> <p>16 Q Turn the page to 72, 73, 74, 75, these are the 17 letters to the editor I was just mentioning.</p> <p>18 A Yes.</p> <p>19 Q Do you see those?</p> <p>20 A Yes.</p> <p>21 Q Do you understand all of those letters were 22 written by paid plaintiffs' experts?</p> <p>23 MS. PARFITT: Objection. Asked and 24 answered.</p> <p>25 A Yes.</p>	<p>Page 55</p>	<p>1 I evaluate their papers the same as I 2 evaluate any other papers in terms of the rigor of 3 their approach, the methodologies that they use, 4 the analysis that they do, and the conclusions 5 they draw from their results. That is how I 6 analyze the papers and how I include them in the 7 reports.</p> <p>8 I am more critical of, like I said, the 9 reviews that are not invited reviews that tend to 10 just be, you know, open responses or letters to 11 the editor and those sorts of things, which is why 12 I included them in the separate section just 13 because, again, I feel differently about people 14 who are designing and analyzing their own 15 independent studies, versus just kind of 16 summarizing, oftentimes in a way that seems to 17 lack any structure, summarizing their opinions.</p> <p>18 That is really why I distinguish those 19 separate sections. And it's a different means of 20 evaluating them.</p> <p>21 MS. PARFITT: Scott, we have been going 22 about an hour. I don't want to interrupt a trend 23 or the middle of your questioning.</p> <p>24 Can we take a break?</p> <p>25 MR. JAMES: I would like to finish this</p>	<p>Page 57</p>

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<p>1 line. I have just a couple more.</p> <p>2 MS. PARFITT: Yes.</p> <p>3 Q With respect to plausibility, you cited and</p> <p>4 emphasized the Fletcher, the Mandarino, the</p> <p>5 McDonald and Johnson studies.</p> <p>6 All of those studies are ones we just cited</p> <p>7 as studies by experts who have been retained and</p> <p>8 paid by plaintiffs.</p> <p>9 Are you aware of that?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 A I am.</p> <p>12 Q Does it concern you that the materials you are</p> <p>13 relying on for plausibility are authored by paid</p> <p>14 plaintiffs' experts?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 A No. Those are only a subset of the materials that</p> <p>17 I'm relying upon for plausibility. Many of the</p> <p>18 other papers in there looking at things like the</p> <p>19 actual talc migration were done in, like,</p> <p>20 retrograde menstruation and some evidence that</p> <p>21 there is, you know, this bidirectional flow, those</p> <p>22 were done years, decades in the 1950s prior to any</p> <p>23 of this talc litigation.</p> <p>24 Q Okay.</p> <p>25 MR. JAMES: Let's take a break.</p>	<p>Page 58</p> <p>1 inactivity, hormone therapy duration, talc use on</p> <p>2 genital areas, and PID appear to be driving the</p> <p>3 higher overall distribution..."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q You were referring in this paper to talc as an</p> <p>7 inflammation-related exposure, fair?</p> <p>8 A That is correct.</p> <p>9 Q Turn to Page 7, Dr. Cote.</p> <p>10 A Yes.</p> <p>11 Q Do you see under the Competing Interests section</p> <p>12 it says, "The authors declare no competing</p> <p>13 interests." Correct?</p> <p>14 A Yes.</p> <p>15 Q So you do not have a conflict of interest declared</p> <p>16 in this paper, correct?</p> <p>17 A Correct.</p> <p>18 Q You got retained, I think, you told me you were</p> <p>19 first contacted early 2023. You had those calls</p> <p>20 we talked about in March of 2023.</p> <p>21 The byline of this paper says it was received</p> <p>22 March 2023, revised July 2023, accepted July 2023</p> <p>23 and published August of 2023.</p> <p>24 Do you see that?</p> <p>25 A Yes.</p>
<p>1 (OFF RECORD AT 10:06 A.M.)</p> <p>2 (AT THIS TIME A SHORT RECESS WAS HELD OFF</p> <p>3 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS</p> <p>4 WERE HAD:)</p> <p>5 (ON RECORD AT 10:13 A.M.)</p> <p>6 BY MR. JAMES:</p> <p>7 Q Are you ready to go?</p> <p>8 A Yes.</p> <p>9 Q In 2023 you authored a paper entitled Association</p> <p>10 of Inflammation Related Exposures.</p> <p>11 Do you recall that article?</p> <p>12 A No. I would like to see it.</p> <p>13 Q Of course. I will mark that as Exhibit Number 4.</p> <p>14 (EXHIBIT NUMBER 4 WAS MARKED FOR</p> <p>15 IDENTIFICATION.)</p> <p>16 A Oh, yes. The survivor study.</p> <p>17 Q Again, this is a paper that you are an author on?</p> <p>18 A Correct.</p> <p>19 Q This article includes multiple references to</p> <p>20 talc, correct?</p> <p>21 A It does.</p> <p>22 Q Look at Page 5 of the article, left column, bottom</p> <p>23 paragraph.</p> <p>24 A Yes.</p> <p>25 Q It says, "Characteristics such as physical</p>	<p>Page 59</p> <p>1 Q So this paper came out after you were retained,</p> <p>2 correct?</p> <p>3 MS. PARFITT: Objection.</p> <p>4 A No. No, it did not. I did not really take on</p> <p>5 this work, as you can see from my invoices, until</p> <p>6 really into September.</p> <p>7 Q You were invoicing for time for which you got paid</p> <p>8 by plaintiffs' counsel as early as March 2023,</p> <p>9 correct?</p> <p>10 A But I had not formed any opinion.</p> <p>11 Q But you were still serving as an expert, correct?</p> <p>12 MS. PARFITT: Objection. Misstates her</p> <p>13 testimony.</p> <p>14 A No. I was reviewing the literature, but I was not</p> <p>15 yet engaged as an expert, no.</p> <p>16 Q Okay. So by August 2023 had you reached the</p> <p>17 opinion that talc causes cancer?</p> <p>18 A No. You will note from my invoicing that pretty</p> <p>19 much over the summer I did, you know, very little,</p> <p>20 very little work in this area.</p> <p>21 Q So your position is that you did not need to</p> <p>22 declare a conflict of interest because you had not</p> <p>23 reached a general causation opinion by the time</p> <p>24 this paper published, correct?</p> <p>25 A Yes.</p>

16 (Pages 58 - 61)

<p style="text-align: right;">Page 62</p> <p>1 Q If you published this paper this year would you 2 issue a conflict of interest statement? 3 A Yes. 4 Q That is because one of topics in the paper is a 5 topic on which you comment in your litigation 6 report, correct? 7 MS. PARFITT: Objection. Form. 8 A You said one of the topics in the paper. 9 Q Sure. 10 A What are you referring to? 11 Q I will do a better job. 12 Again, you were referring in this paper to 13 talc as an inflammation-related exposure, is that 14 correct? 15 A Yes, but not in the sense of exposure in terms of 16 something that initiates disease. This is a very 17 different outcome we are looking at. 18 This is ovarian cancer survival. I should 19 also note that this paper is actually kind of a 20 replication of a study. This is all 21 African-American or Black women. This paper is a 22 replication study. 23 The entire inflammatory index and everything 24 was developed not by me personally. There may 25 have been some of the other authors on the</p>	<p style="text-align: right;">Page 64</p> <p>1 A No, I do not. 2 Q Do you think the readers of this paper are 3 entitled to know that one of the authors was 4 working as a paid expert at the time that this 5 paper came out? 6 MS. PARFITT: Objection. Misstates her 7 responses. 8 A I did not create this index. I was, I am not a 9 primary person on this. And in my mind I had not 10 yet reached an opinion as to whether or not talc 11 can cause ovarian cancer, which is a very 12 different question than whether talc is associated 13 with poor survival or improved survival, for that 14 point, after an ovarian cancer diagnosis. 15 So we are looking at a very different 16 outcome. 17 Q You are a member of the African-American Cancer 18 Epidemiology Study Group, correct? 19 A Correct. It's not really a study group. It was a 20 grant. It is a grant, yes. 21 Q Are there any plans with the AACES to do further 22 studies on talc? 23 A I do not believe so. Simply because, again, where 24 we have shifted is from looking at incidence of 25 disease or etiology of disease, which some of the</p>
<p style="text-align: right;">Page 63</p> <p>1 original paper. But it is this -- I'm sorry -- 2 her name is Catherine -- I have to find it again. 3 B-R-I-E-G-E-R. That is Reference Number 13. 4 And actually Number 14 is the one where she 5 developed this inflammation-related risk score. 6 So what we did was that study was in primarily 7 White women. 8 We took that risk score and tried to apply it 9 to our African-American case control study. 10 Q Regardless, you would agree that if you wrote this 11 paper today you would include a conflict of 12 interest disclosure, correct? 13 A Yes. 14 Q And do the co-authors of this paper know that you 15 are doing work for plaintiffs on the talc 16 litigation? 17 MS. PARFITT: Objection to form. 18 A No, I don't believe so. 19 Q Is there some sort of mechanism that would allow 20 you to contact the Journal to allow you to add the 21 disclosure in the online version? 22 A I don't know. I have never thought about it. If 23 I -- I could contact the Journal, I imagine. 24 Q Do you think it would be appropriate to do so? 25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 65</p> <p>1 earlier papers like the Schildkraut 2016 paper 2 into survivorship issues. This paper here more or 3 less captures kind of a more comprehensive way to 4 examine inflammation. 5 So I do not -- I have not heard that anybody 6 is interested in doing anything talc specific in 7 this group. 8 Q Again, for this Johnson study in your report you 9 do comment on talc as an inflammation-related 10 exposure, both for the initiation and the 11 progression of ovarian cancer, right? 12 A It can be potentially, yes. I'm not sure where I 13 say that in the report. 14 Q Your testimony today is that you think it can? 15 A Potentially it can be. But I've not done a 16 systematic review looking at progression, 17 recurrence, cancer specific survival. 18 Q Do you intend to advise the AACES colleagues that 19 you are now doing paid expert work for the 20 plaintiffs in the talc litigation? 21 A Yes, I'm comfortable to do so. 22 Q You will do so if you write any more papers on 23 issues relevant to the litigation, fair? 24 A Fair. 25 Q Other than Schildkraut 2016, have you authored any</p>

<p style="text-align: right;">Page 66</p> <p>1 papers that assess the association between talc 2 and ovarian cancer?</p> <p>3 A Ovarian cancer incidence meaning?</p> <p>4 Q Yes.</p> <p>5 A No, that is it.</p> <p>6 Q Have you authored any other papers other than 7 Schildkraut and Johnson that assess an association 8 between talc and ovarian cancer in any way?</p> <p>9 A No.</p> <p>10 Q Have you submitted any portion of your litigation 11 report or the substance of your litigation report 12 for peer review?</p> <p>13 A No.</p> <p>14 Q Do you intend to work on any articles related to 15 talc?</p> <p>16 A Do I intend to work on any articles related to 17 talc?</p> <p>18 Q I can be more specific.</p> <p>19 A Yes, please.</p> <p>20 Q Do you intend to work on any articles related to 21 talc and ovarian cancer?</p> <p>22 A At this point in time I am mostly interested in 23 publishing novel data and novel analyses. So I 24 don't have any specific plans to -- we are not 25 going to develop a new cohort or case control</p>	<p style="text-align: right;">Page 68</p> <p>1 and I guess Johnson -- have you ever given any 2 presentation, speeches, or lectures concerning 3 talc and ovarian cancer or asbestos and ovarian 4 cancer?</p> <p>5 A No, I have not.</p> <p>6 Q Have you ever given any statements or interviews 7 related to talc and ovarian cancer or asbestos and 8 ovarian cancer?</p> <p>9 A No, I have not.</p> <p>10 Q Have you ever authored any internet postings or 11 blogs related to talc and ovarian cancer or 12 asbestos and ovarian cancer?</p> <p>13 A No, I have not.</p> <p>14 Q Have you ever prepared or used any teaching 15 materials for your students or in your 16 professional life concerning talc and ovarian 17 cancer or asbestos and ovarian cancer?</p> <p>18 A No, I don't believe so.</p> <p>19 Q Okay. And when I think of teaching materials, I 20 think of things like slides or PowerPoints or 21 charts.</p> <p>22 Is there anything like that that you have 23 done in your professional history?</p> <p>24 A No.</p> <p>25 Q Have you ever talked with any health care</p>
<p style="text-align: right;">Page 67</p> <p>1 study that is going to be able to address this 2 question in a meaningful way. So, no, I don't 3 believe I will.</p> <p>4 Q If you did so, you would declare a conflict of 5 interest, correct?</p> <p>6 A Yes.</p> <p>7 Q You believe that would be the proper thing to do 8 for any expert working in talc litigation to 9 declare a conflict of interest on a paper?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 A I can only speak personally what I would do.</p> <p>12 Q You would personally be governed by the disclosure 13 requirements of the Journal as well?</p> <p>14 A Correct. They all have different requirements.</p> <p>15 Q As a scientist you can understand how working in a 16 litigation as a paid expert could be perceived as 17 a conflict of interest, correct?</p> <p>18 MS. PARFITT: Object to form.</p> <p>19 A Yes, I understand it can be perceived as a 20 conflict of interest. That is why we do list 21 them.</p> <p>22 Q Have you ever authored any papers on asbestos and 23 ovarian cancer?</p> <p>24 A No, I've not.</p> <p>25 Q Have you ever given any -- outside of Schildkraut</p>	<p style="text-align: right;">Page 69</p> <p>1 professionals to tell their patients to stop using 2 talc?</p> <p>3 MS. PARFITT: Objection. Form.</p> <p>4 A No, I have not.</p> <p>5 Q Have you ever suggested to a health care 6 professional that they assess a patient's risk for 7 ovarian cancer based upon prior talc usage?</p> <p>8 MS. PARFITT: Objection to form.</p> <p>9 A No, I have not. I came to this conclusion about 10 four months ago.</p> <p>11 I'm trying to think if I have even interacted 12 with any sort of clinical professional in the last 13 four months. I don't think I have.</p> <p>14 Q Understood. Have you ever talked with any health 15 care professionals to suggest that they consider 16 offering risk reducing surgeries for prior talc 17 users?</p> <p>18 A No.</p> <p>19 Q Have you ever talked to any health care 20 professionals to encourage them to use additional 21 screening or monitoring for ovarian cancer based 22 upon prior talc usage?</p> <p>23 A No.</p> <p>24 Q Have you ever talked with any, or had any 25 communications with any public health agencies or</p>

<p style="text-align: right;">Page 70</p> <p>1 scientific or medical organizations or regulatory 2 bodies about talc and ovarian cancer or asbestos 3 and ovarian cancer?</p> <p>4 MS. PARFITT: Objection. Compound.</p> <p>5 A No. No to both.</p> <p>6 Q In your report you state that certain prophylactic 7 surgeries or procedures can be offered as a risk 8 reduction strategy for women who have known 9 inherited mutations, right?</p> <p>10 A Correct.</p> <p>11 Q Are you aware of any health care institution or 12 physician or organization that counsels on or 13 recommends prophylactic surgeries as a means of 14 risk reduction for cancer for prior talc users?</p> <p>15 A I'm unaware of any. But, again, I also have not 16 asked that question.</p> <p>17 Q Okay. Are you aware of any health care 18 institution or organization that counsels or 19 recommends additional cancer screenings for prior 20 talc users?</p> <p>21 A I'm unsure what kind of screening you would be 22 referring to because there is not really 23 population-based broad screening for ovarian 24 cancer.</p> <p>25 So there is really no screening to even</p>	<p>1 Q Have you ever discussed the topic of talc and 2 ovarian cancer with anyone at Komen?</p> <p>3 A No.</p> <p>4 Q I'm shorthanding that. We are discussing Susan G. 5 Komen, correct?</p> <p>6 A Correct. Yes.</p> <p>7 Q Do you have an opinion on the number of ovarian 8 cancer cases diagnosed per year that you believe 9 could be attributed to talc usage?</p> <p>10 A So, again, this goes back to my expert report.</p> <p>11 These were estimates provided by Wu. He was 12 looking at three different populations.</p> <p>13 He was looking African-American -- the same 14 population in California, but African-American 15 women, Hispanic women, and non-Hispanic White 16 women. He came up with estimates of population 17 attributable risk, which essentially means if you 18 removed said exposure from the population it would 19 reduce the number of cases by a certain number.</p> <p>20 He quoted for those three different 21 populations between about twelve and 22 fifteen percent reduction. So, you know, if you 23 look at, you know, I have to do hard math, you 24 know, if you were going to say, like, there's 25 approximately 12,000 cases every year, you could</p>
<p style="text-align: right;">Page 71</p> <p>1 offer.</p> <p>2 Q And just to wrap that up. Again, are you aware of 3 anyone who, any organization or institution that 4 recommends doing so?</p> <p>5 That recommends additional screening or 6 monitoring for ovarian cancer based upon prior 7 talc usage?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 A No, I'm not.</p> <p>10 Q Are you aware of any health care institution or 11 physician or medical or scientific organization 12 that inquires about patient's prior talc usage to 13 assess cancer risks?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 A No. I'm not aware of that, but, again, I don't 16 believe that there is any sort of model that is 17 currently being used clinically that has been 18 validated in multiple populations such as we have 19 some of those models for, like, breast cancer.</p> <p>20 There is the Gail Model and the IBIS model. 21 Those are used clinically to assess risk. I don't 22 believe anything like that exists for ovarian.</p> <p>23 Q Are you aware of any biomarker that exists for 24 talc usage?</p> <p>25 A No. I'm not aware of any biomarker.</p>	<p style="text-align: right;">Page 73</p> <p>1 say that somewhere between 1,200 and perhaps 1,500 2 or 1,600, and excuse me if my math is not perfect 3 there, that would be attributable to talc.</p> <p>4 If you removed talc from the population you 5 would remove that on an annual basis.</p> <p>6 Q Do you hold that opinion, or is that something 7 that you just read?</p> <p>8 A Well, I have never done those calculations myself. 9 You know, using data from our AACEs study, for 10 example, population attributable risk includes 11 exposure, like, the percent exposed in the 12 population is a very big component of that.</p> <p>13 So in something like the AACEs population, 14 the African-American women were the higher risk 15 estimate, attributable risk estimate there.</p> <p>16 I believe that those estimates have, they 17 have utility when you are trying to plan for 18 public health interventions and those sorts of 19 things.</p> <p>20 So I do believe that, you know, that the 21 estimates provided in the Wu paper are, you know, 22 calculated based on a large number of participants 23 and are probably valid calculations. So I would 24 stand by those.</p> <p>25 Q Are you aware that one of the plaintiffs' experts</p>

<p>1 in this litigation has attributed between 2,300 2 and 6,500 ovarian cancer cases a year to talc 3 usage?</p> <p>4 Are you aware of that, yes or no?</p> <p>5 MS. PARFITT: Objection.</p> <p>6 A Can you tell me what years that was from?</p> <p>7 Ovarian cancer has been decreasing slightly 8 in the community. Talc use has been decreasing 9 substantially in the community.</p> <p>10 So I'm wondering what years those were quoted 11 from?</p> <p>12 Q Let me just rephrase the question.</p> <p>13 A Okay.</p> <p>14 Q Based upon 2023 diagnoses for ovarian cancer, do 15 you think it's in any way scientifically valid to 16 claim that between 2,300 and 6,500 cases of 17 ovarian cancer a year are attributable to talc 18 usage?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 A Again, you know, based on we don't have data 21 really for talc use in the population in 2023. We 22 don't have, you know, we are not talking about the 23 breakdown by race and ethnicity. I think there 24 was some discussion that Black women are more 25 likely to use talc. Those numbers are not outside</p>	Page 74	<p>1 population.</p> <p>2 To me that would be maybe at the end of the 3 range, but not wildly outside of it.</p> <p>4 Q Sitting here today, have you calculated an 5 attributable risk for ovarian cancer?</p> <p>6 A I've not, no.</p> <p>7 Q Your Appendices A is your C.V., correct, to your 8 report?</p> <p>9 A I believe so. I'm there.</p> <p>10 Q I see that from 2016 to 2022 you were the 11 associate center director for cancer research at 12 Karmanos, correct?</p> <p>13 A Cancer research training and education was the 14 final name of that. Yes. It's very different 15 than for just cancer research.</p> <p>16 This was more about mentoring junior faculty 17 and all levels of trainees to make sure that they 18 had the things that they needed to succeed in a 19 faculty role.</p> <p>20 Q Did you ever teach at Karmanos on talc and ovarian 21 cancer?</p> <p>22 A I taught at Wayne State University.</p> <p>23 Q Okay.</p> <p>24 A I taught introductory classes in epidemiology. I 25 never specifically taught on talc and ovarian</p>	Page 76
<p>1 of the ballpark. No.</p> <p>2 Q Do you think there is any consensus in the medical 3 and scientific community that up to 6,000 cases of 4 ovarian cancer diagnosed every year are 5 attributable to talcum powder?</p> <p>6 MS. PARFITT: Objection. Asked and 7 answered.</p> <p>8 A Again, you know, 6,000, so that out of the, you 9 know, between 12,000 and 13,000 that will 10 probably, you know, be diagnosed, I know they were 11 diagnosed in 2023 but we don't really have those 12 data complete yet, saying that almost fifty 13 percent would be attributable to talc or could be 14 if talc were removed, you know, from the 15 population that we would not have seen those 16 cases, I don't believe that there is consensus.</p> <p>17 But I think the other consideration is just 18 not just what is going on in the U.S. but what is 19 going on worldwide. Certainly, worldwide those 20 numbers would be absolutely valid.</p> <p>21 Q My question specifically is about the 22 United States.</p> <p>23 A Okay. No. Again, we don't have those data. We 24 don't know about talc usage in the population 25 overall, you know, the cases and the general</p>	Page 75	<p>1 cancer, no.</p> <p>2 Q At either Wayne State or Karmanos, is that 3 correct?</p> <p>4 A Correct. But Karmanos is not a teaching 5 institution in that regard, like, didactic 6 teaching.</p> <p>7 Q Are you aware -- you were at Karmanos for a long 8 time, correct?</p> <p>9 A Correct. Over twenty years.</p> <p>10 Q Are you aware of whether Karmanos maintains a 11 public-facing webpage to provide information and 12 resources on ovarian cancer?</p> <p>13 A I'm not aware as to whether or not they do.</p> <p>14 Q Is that something that you have ever looked at?</p> <p>15 A Have I looked at the Karmanos website for that, 16 no.</p> <p>17 (EXHIBIT NUMBER 5 WAS MARKED FOR 18 IDENTIFICATION.)</p> <p>19 Q I will hand you what I have marked as Exhibit 20 Number 5.</p> <p>21 You can see that is a document titled, 22 Ovarian Cancer Treated at Karmanos.</p> <p>23 Do you see that?</p> <p>24 A Yes.</p> <p>25 Q Have you ever looked at this page?</p>	Page 77

<p style="text-align: right;">Page 78</p> <p>1 A No, not that I recall.</p> <p>2 Q If you flip to the second page you can see it</p> <p>3 identifies the gynecologic oncologists that treat</p> <p>4 ovarian cancer, correct?</p> <p>5 A Correct. Yes. And other female cancers, sure.</p> <p>6 Q We see here on the first page under Treatment of</p> <p>7 Ovarian Cancer that Karmanos refers to information</p> <p>8 from the National Cancer Institute.</p> <p>9 Do you see that on the first page?</p> <p>10 A Sure. Yes.</p> <p>11 Q It says, "Includes information about ovarian</p> <p>12 cancer, causes, risk factors, diagnosis and</p> <p>13 treatment."</p> <p>14 Do you see that?</p> <p>15 A I do.</p> <p>16 Q And when you click on that link it links you to</p> <p>17 the NCI PDQ.</p> <p>18 Are you aware of that?</p> <p>19 A I would assume that is where it goes. Yes, I know</p> <p>20 the PDQ.</p> <p>21 Q Do you think Karmanos' decision to links its</p> <p>22 patients to the NCI PDQ for information on ovarian</p> <p>23 cancer causes and risk factors in a scientifically</p> <p>24 sound decision?</p> <p>25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 80</p> <p>1 sections on What is ovarian cancer? Who can get</p> <p>2 ovarian cancer? The symptoms, and then on the</p> <p>3 third page, How do I lower my risk for ovarian</p> <p>4 cancer?</p> <p>5 Do you see that?</p> <p>6 A Yes, I do.</p> <p>7 Q Is this a page that you have seen before?</p> <p>8 A No, it's not.</p> <p>9 Q And you can see under the section, Who can get</p> <p>10 ovarian cancer, if you flip to the second page, do</p> <p>11 you see they list risk factors?</p> <p>12 A They list some of the risk factors, yes.</p> <p>13 Q Is talc mentioned there?</p> <p>14 A No. Talc is not mentioned there, but neither is</p> <p>15 something like obesity.</p> <p>16 Q But talc is not mentioned?</p> <p>17 A Correct, it's not. But it does not appear to be a</p> <p>18 comprehensive list of things that might increase</p> <p>19 your risk.</p> <p>20 In fact --</p> <p>21 Q Are you critical of the information that Karmanos</p> <p>22 puts out?</p> <p>23 A I go back to the statement that I have not</p> <p>24 reviewed this until just now. I don't know the</p> <p>25 process they use for getting this. Yes, it</p>
<p style="text-align: right;">Page 79</p> <p>1 A Scientifically sound decision? I can't really</p> <p>2 judge whether or not it is a scientifically sound</p> <p>3 decision because I don't know the science or the</p> <p>4 methodology behind how the NCI pulls all of these</p> <p>5 data together.</p> <p>6 I can't give an opinion as to whether or not</p> <p>7 it's scientifically sound.</p> <p>8 Q Is Karmanos wrong to link its patients to the NCI</p> <p>9 PDQ?</p> <p>10 MS. PARFITT: Objection to the form.</p> <p>11 A I have no opinion as to whether Karmanos is right</p> <p>12 or wrong, again, because I don't know exactly the</p> <p>13 methodology behind how NCI puts together these PDQ</p> <p>14 pages, how frequently they review them, and so on.</p> <p>15 I did include a couple of these in my expert</p> <p>16 report. It comes up when you Google for things.</p> <p>17 Q Sure. We will get to the PDQ shortly.</p> <p>18 Are you aware that Karmanos also publishes a</p> <p>19 page on ovarian cancer facts and prevention?</p> <p>20 A No, I'm not aware of that.</p> <p>21 Q I will mark that as Exhibit 6.</p> <p>22 (EXHIBIT NUMBER 6 WAS MARKED FOR</p> <p>23 IDENTIFICATION.)</p> <p>24 A Okay.</p> <p>25 Q And, Dr. Cote, you can see here that they have</p>	<p style="text-align: right;">Page 81</p> <p>1 appears to me one of the biggest factors here that</p> <p>2 they don't mention is knowledge of a BRCA1 or 2</p> <p>3 mutation or Lynch syndrome.</p> <p>4 They talk about family history. They don't</p> <p>5 specify that. So I would say that this list is</p> <p>6 incomplete.</p> <p>7 Q Do you think the person who put this together at</p> <p>8 Karmanos exercised sound, scientific, and medical</p> <p>9 judgment?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 A I cannot comment on their scientific rationale and</p> <p>12 judgment because I don't know who put this</p> <p>13 together, whether it was a group of people. I</p> <p>14 don't know if it was just pulled from somewhere</p> <p>15 else.</p> <p>16 I know nothing about where they got this</p> <p>17 information from, or what their credentials were.</p> <p>18 Q If talc caused 6,000 cases of ovarian cancer in</p> <p>19 the United States a year, do you think talc would</p> <p>20 be listed on this document?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 A Again, as I stated, I don't know how they chose</p> <p>23 these risk factors. It's interesting, it really</p> <p>24 looks like everything they have here are kind of</p> <p>25 non-modifiable risk factors.</p>

1 You can't recall when you start menstruation. 2 You can't control your family history. To some 3 extent you can't control whether or not you have 4 children or how many. 5 So it's interesting that the focus here 6 really just looked at non-modifiable risk factors. 7 Q And if you look at Page 3 you can also see there 8 are references to how I lower my risk factors. 9 There is references there to oral contraceptives 10 and breast feeding, correct? 11 A Correct. 12 Q As well as tubal ligation? 13 A Correct. 14 Q When you were at Karmanos and Wayne State were you 15 ever a member of the Gynecologic Oncology Multiple 16 Disciplinary Team? 17 A No, I was not. 18 Q Was that a team that you are familiar with? 19 A It is. 20 Q Do you know Dr. Ira Winer? 21 A I do know Dr. Winer, yes. 22 Q Have you ever -- 23 A We published a paper together. 24 Q Have you ever talked with him about talc and 25 ovarian cancer?	Page 82 1 You can't recall when you start menstruation. 2 You can't control your family history. To some 3 extent you can't control whether or not you have 4 children or how many. 5 So it's interesting that the focus here 6 really just looked at non-modifiable risk factors. 7 Q And if you look at Page 3 you can also see there 8 are references to how I lower my risk factors. 9 There is references there to oral contraceptives 10 and breast feeding, correct? 11 A Correct. 12 Q As well as tubal ligation? 13 A Correct. 14 Q When you were at Karmanos and Wayne State were you 15 ever a member of the Gynecologic Oncology Multiple 16 Disciplinary Team? 17 A No, I was not. 18 Q Was that a team that you are familiar with? 19 A It is. 20 Q Do you know Dr. Ira Winer? 21 A I do know Dr. Winer, yes. 22 Q Have you ever -- 23 A We published a paper together. 24 Q Have you ever talked with him about talc and 25 ovarian cancer?	Page 84 1 Q It says -- it is quoting Dr. Winer. "The 2 available data specific to talc is still 3 questionable." 4 Do you see that? 5 A I do. 6 Q He says, "Some epidemiologic studies show an 7 increase in risk with talc usage while others fail 8 to demonstrate this association. Many of these 9 studies have significant sources of bias which 10 could potentially call the studies' conclusions in 11 question." 12 Do you see that? 13 A I do, yes. 14 Q Dr. Winer goes on to state in a quote, "Two of the 15 largest prospective observational studies, the 16 Women's Health Initiative and Nurses Health Study, 17 did not show a definitive link." 18 Do you see that? 19 A I do, yes. 20 Q Do you agree with Dr. Winer's comment at least in 21 2016 that the data specific to talc was 22 questionable? 23 MS. PARFITT: Objection to form. 24 A I don't necessarily agree with that, no. I would 25 disagree with that statement.
Page 83 1 A No, I don't believe we have. 2 Q Were you ever involved at Karmanos in the 3 publication of a newsletter or a document titled 4 Hope? 5 A No, not that I'm aware of. 6 Q Have you ever reviewed an edition of Hope 7 regarding to talc and ovarian cancer? 8 A Not in my memory, no. 9 Q I will mark this as Exhibit Number 7. 10 (EXHIBIT NUMBER 7 WAS MARKED FOR 11 IDENTIFICATION.) 12 Q This is a publication titled Hope from Karmanos. 13 You can see Exhibit 7 is titled, "The Truth 14 About Talc. Does it cause ovarian cancer?" 15 Do you see that? 16 A I do. 17 Q This is from August 2016, is that correct? 18 A That is true. 19 Q When was the last time you talked with Dr. Winer 20 about anything? 21 Was it before you left? 22 A Probably before then. 23 Q Understood. If you look at Page 1 at the bottom 24 column -- the left column, bottom left. 25 A Yes.	Page 83 1 A No, I don't believe we have. 2 Q Were you ever involved at Karmanos in the 3 publication of a newsletter or a document titled 4 Hope? 5 A No, not that I'm aware of. 6 Q Have you ever reviewed an edition of Hope 7 regarding to talc and ovarian cancer? 8 A Not in my memory, no. 9 Q I will mark this as Exhibit Number 7. 10 (EXHIBIT NUMBER 7 WAS MARKED FOR 11 IDENTIFICATION.) 12 Q This is a publication titled Hope from Karmanos. 13 You can see Exhibit 7 is titled, "The Truth 14 About Talc. Does it cause ovarian cancer?" 15 Do you see that? 16 A I do. 17 Q This is from August 2016, is that correct? 18 A That is true. 19 Q When was the last time you talked with Dr. Winer 20 about anything? 21 Was it before you left? 22 A Probably before then. 23 Q Understood. If you look at Page 1 at the bottom 24 column -- the left column, bottom left. 25 A Yes.	Page 85 1 Q Do you agree with Dr. Winer's comment in 2016 that 2 many of these studies have significant sources of 3 bias? 4 MS. PARFITT: Objection. Form. 5 A Again, because I don't know what types of bias he 6 is referring to or even what studies he is 7 referring to I would say no. I would not support 8 that statement. 9 Q Okay. Turn to Page 2. 10 You can see there is a photograph of 11 Dr. Winer. 12 Do you see that? 13 A Yes. 14 Q At the bottom of that first paragraph in the last 15 sentence he says -- this is a statement he has 16 authored. 17 Do you see his signature? 18 A Yes. 19 Q He says, "As an ovarian cancer researcher and 20 gynecologic oncology specialist, I can say that 21 the current data is mixed and that even if there 22 is a potential link, the absolute risk to any 23 individual woman is likely small. More definitive 24 studies are needed from a biologic and population 25 standpoint."

<p style="text-align: right;">Page 86</p> <p>1 Do you see that?</p> <p>2 A Yes.</p> <p>3 Q Would you agree with Dr. Winer's comment in 2016</p> <p>4 that the current data is mixed?</p> <p>5 MS. PARFITT: Objection.</p> <p>6 A No. I believe that the epidemiologic evidence</p> <p>7 even in 2016 was fairly consistent and strong. I</p> <p>8 would not say it was overly mixed.</p> <p>9 Q Would you agree with Dr. Winer's comment in 2016</p> <p>10 that the absolute risk to any individual woman is</p> <p>11 likely small?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A I would say that talc is a modifiable risk factor</p> <p>14 that, as Dr. Winer knows better than I, is an</p> <p>15 absolutely devastating disease for women and</p> <p>16 families. Cancer happens to individuals, but it</p> <p>17 affects the family and it affects the community.</p> <p>18 Any increase in risk, whether it is small --</p> <p>19 with respect to a product that does not have any</p> <p>20 sort of medicinal benefit, that it is not small.</p> <p>21 So I would disagree there, too. That</p> <p>22 absolute risk to any individual is likely small is</p> <p>23 perhaps his opinion.</p> <p>24 But I think, further, it would -- it's an</p> <p>25 avoidable risk.</p>	<p style="text-align: right;">Page 88</p> <p>1 question.</p> <p>2 You can see here below that, like Karmanos,</p> <p>3 the AACR is linking to the NCI PDQ for ovarian</p> <p>4 cancer prevention, correct?</p> <p>5 A Yes, that is correct.</p> <p>6 Q Do you believe that the AACR is wrong in linking</p> <p>7 its audience to the NCI PDQ for information on</p> <p>8 ovarian cancer?</p> <p>9 MS. PARFITT: Objection.</p> <p>10 A I have no opinion as to whether or not the AACR is</p> <p>11 right or wrong in terms of what they choose to</p> <p>12 link to.</p> <p>13 Q You have significant ties to the NCI, correct?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 A Define significant.</p> <p>16 Q Sure. I see from your C.V. that you have been a</p> <p>17 reviewer for the NCI, correct?</p> <p>18 A Yes.</p> <p>19 Q You have chaired at least two NCI committees,</p> <p>20 correct?</p> <p>21 A Yes.</p> <p>22 Q You have served as editor and a manuscript</p> <p>23 reviewer for the JNCI, correct?</p> <p>24 A Yes. The JNCI specifically says that they are not</p> <p>25 a Journal of the National Cancer Institute. They</p>
<p style="text-align: right;">Page 87</p> <p>1 Q I see from your C.V. you are also affiliated with</p> <p>2 the AACR, correct?</p> <p>3 A Yes. I'm a long-time member of AACR.</p> <p>4 Q Are you aware that the AACR maintains a</p> <p>5 public-facing page to provide patients information</p> <p>6 about ovarian cancer?</p> <p>7 A I don't believe I have ever looked at that page,</p> <p>8 no.</p> <p>9 Q I will mark the AACR page titled Ovarian Cancer as</p> <p>10 Exhibit Number 8.</p> <p>11 (EXHIBIT NUMBER 8 WAS MARKED FOR</p> <p>12 IDENTIFICATION.)</p> <p>13 Q Dr. Cote, is this a page or a website that you</p> <p>14 have ever seen before?</p> <p>15 A No. I have not seen this simply because this is</p> <p>16 not where I go for my research information.</p> <p>17 Q Do you understand that this is put out by the AACR</p> <p>18 to provide resources to patients and the like,</p> <p>19 correct?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 A I understand that AACR has this website. What the</p> <p>22 goal is I'm not sure. I note that the source of</p> <p>23 this is the National Cancer Institute, which is</p> <p>24 fairly broad.</p> <p>25 Q As you can see -- that transitions to my next</p>	<p style="text-align: right;">Page 89</p> <p>1 consider themselves distinct entities.</p> <p>2 Q My shorthand was incorrect.</p> <p>3 The Journal of the National Cancer Institute,</p> <p>4 correct?</p> <p>5 A Yes.</p> <p>6 Q That is what it's called?</p> <p>7 A It is. But look at their footnotes. They say</p> <p>8 that they are independent of the National Cancer</p> <p>9 Institute.</p> <p>10 Q Understood. I was clarifying that I meant Journal</p> <p>11 when I said J.</p> <p>12 You note in your report that you have been</p> <p>13 supported by the NCI. You have reviewed programs</p> <p>14 for the NCI. You have sat on panels for NCI</p> <p>15 designated comprehensive cancer centers, correct?</p> <p>16 A Yes.</p> <p>17 Q Do you hold the NCI in high regard?</p> <p>18 A Yes.</p> <p>19 Q Do you consider the NCI to be a highly respected</p> <p>20 cancer research organization?</p> <p>21 A I believe that NCI does some outstanding research,</p> <p>22 but they are also a government organization. They</p> <p>23 have kind of got two branches, an intramural and</p> <p>24 extramural.</p> <p>25 Their intramural researchers do cancer</p>

<p style="text-align: right;">Page 90</p> <p>1 research and I have high regard for many of my 2 colleagues there. The external branch is more of 3 a, they facilitate and fund scientific research 4 all around the country and, in fact, the world. 5 So there are kind of two different branches 6 when you talk about NCI. There is one that is 7 more research. There is one that more funds 8 research. That research is vetted by the study 9 sections and things that we do. 10 So it's two different things. I do think for 11 the discussion here that they are both highly 12 regarded as mechanisms for funding, as well as for 13 scientific research, yes.</p> <p>14 Q Do you believe that information made available to 15 the public by the NCI and linked by Karmanos, by 16 the AACR, and by other organizations that we have 17 looked at, do you believe that information made 18 available by the NCI can be trusted by health care 19 professionals and patients as credible 20 information?</p> <p>21 MS. PARFITT: Objection to form.</p> <p>22 A I believe it does contain some credible 23 information. I also believe, just as I mentioned 24 with some of the Karmanos documents that we 25 showed, that the information is sometimes</p>	<p style="text-align: right;">Page 92</p> <p>1 MS. PARFITT: If you need to reference 2 your documents, you may. 3 A "Results from case control and cohort studies are 4 inconsistent." 5 Q On the prior, without -- I'm not trying to put the 6 report in your mouth. Just the document in front 7 of you, if you can see the PDQ, whether you agree 8 with it or not. 9 A Correct. 10 Q Here you can see on the prior page there is a 11 title Factors with Inadequate Evidence. 12 Do you see that? 13 A Yes. 14 Q You can see that following this section there are 15 a number of factors listed. 16 Perineal talc exposure is in that bucket, 17 fair? 18 A Fair. 19 Q You can see here, and you just mentioned it, that 20 the NCI PDQ reports that "Results from case 21 control and cohort studies are inconsistent, so 22 the data are inadequate to support an association 23 between perineal talc exposure and an increased 24 risk of ovarian cancer." 25 Did I read that correctly?</p>
<p style="text-align: right;">Page 91</p> <p>1 incomplete. 2 Q I will mark as Exhibit Number 9 the NCI PDQ. 3 (EXHIBIT NUMBER 9 WAS MARKED FOR 4 IDENTIFICATION.) 5 A Yes. 6 Q As you mentioned, you do discuss this document in 7 your report, correct? 8 A Correct. 9 Q We see here this is the PDQ dedicated to ovarian 10 cancer prevention, correct? 11 A Yes. 12 Q And if we look at, this is not paginated, but if 13 you go about four pages before the end. 14 A Yes. I assume you are wanting -- 15 Q The Perineal Talc Exposure. 16 A Got it. 17 Q Again, from your report I can see you are familiar 18 with the fact that the PDQ identifies perineal 19 talc exposure as a factor with an adequate 20 evidence of an association, correct? 21 A I will assume that is correct. Let me look at my 22 report. 23 Q I can rephrase the question. If you just look at 24 the page prior to that. 25 A Okay.</p>	<p style="text-align: right;">Page 93</p> <p>1 A You read that correctly, yes. 2 Q I understand you disagree with the NCI, correct? 3 MS. PARFITT: Objection to form. 4 A I disagree with the NCI with respect to this 5 particular statement, yes. 6 Q Fair enough. Do you question the objectivity and 7 the scientific credibility of the panel and board 8 members who compiled this PDQ document? 9 MS. PARFITT: Object to form. 10 A I don't necessarily question their objectivity or 11 their qualifications. I just know nothing about 12 their methodology for how they came to these 13 conclusions. 14 Because when I look at this, you know, and I 15 see their references here for this section, they 16 only have a total of fourteen references. The 17 ones that are specific to talc are only seven. So 18 only maybe -- yeah, seven. 19 So it's very unclear to me how they selected 20 just these seven out of the four decades' worth of 21 research. 22 So I don't understand their methods so I 23 don't feel like I can really comment on whether I 24 feel that they, themselves, are inadequate or not 25 prepared.</p>

<p style="text-align: right;">Page 94</p> <p>1 Q Are you suggesting that the NCI PDQ panel and 2 board members only considered these seven items? 3 MS. PARFITT: Objection. Form. 4 A I have no idea what they considered and what went 5 into forming, you know, their opinion here because 6 there are not any specifics about how they came to 7 this conclusion outside of these references. 8 Q Have you looked at the history of the PDQ document 9 to see if the PDQ has referred to additional 10 literature along the way? 11 A I've not gone back in time and looked at the 12 history. I'm not sure how I would do that being 13 that things are updated. 14 Q Are you questioning the thoroughness of the 15 NCI PDQ panel members in reviewing the literature 16 and commenting on the association between talc and 17 ovarian cancer? 18 MS. PARFITT: Objection. 19 A I'm questioning the methodology used because it's 20 unclear. I'm not questioning the reviewers, their 21 expertise. 22 Q If you can look to the second to last page with 23 me, Dr. Cote. 24 A Yes. 25 Q At the top of the page it says Latest Updates.</p>	<p style="text-align: right;">Page 96</p> <p>1 Do you acknowledge that they cite the Woolen 2 article? 3 A They do, yes, they do cite Woolen. But they do 4 not cite Phung. 5 Q Phung is the article you discussed earlier as 6 related to endometriosis? 7 A Correct. Yes. 8 Q Then at the bottom of the page that says Latest 9 Updates, do you see that? 10 A Yes. 11 Q That is the second to the last page. 12 It says, "Board members review recently 13 published articles each month..." 14 Do you see that? 15 A I do. 16 Q Do you have any reason to question that? 17 MS. PARFITT: Objection. Form. 18 A I have no reason to question whether or not -- or 19 when they review or their schedule of review, no. 20 Q Do you have any reason to disagree with the 21 statement that changes to the summary are made 22 through consensus process in which board members 23 evaluate the strength of the evidence and 24 published articles? 25 MS. PARFITT: Objection.</p>
<p style="text-align: right;">Page 95</p> <p>1 Do you see that? 2 A Yes. 3 Q Excellent. We see here that it says the summary 4 was most recently updated on March 6, 2024, 5 correct? 6 A Correct. 7 Q This is a couple weeks ago, correct? 8 A Yes. Correct. 9 Q You see below here that under the Reviewers and 10 Updates section it says, "This summary is reviewed 11 regularly and updated as necessary by the PDQ 12 Screening and Prevention Editorial Board." 13 Did I read that correctly? 14 A Yes. 15 Q Do you have any reason to question whether or not 16 the summary is reviewed regularly? 17 MS. PARFITT: Objection. Form. 18 A Again, I guess I would ask, what is regularly? I 19 don't have any idea what their methodology is. 20 Q You do understand that they cite the most recent 21 meta-analysis on the topic of talc and ovarian 22 cancer, correct? 23 MS. PARFITT: Objection. 24 A The most recent being Phung? 25 Q That's a fair point.</p>	<p style="text-align: right;">Page 97</p> <p>1 A I have no reason to question that that does or 2 does not occur. 3 Q Do you have any reason to question that the board 4 makes determinations on how or whether articles 5 should be included in the summary? 6 MS. PARFITT: Objection. Form. 7 A I still question how they come to that decision. 8 They don't describe where they find, you know -- 9 they just say recently published articles each 10 month. They don't describe who brings those 11 articles. They don't describe, you know, really 12 any process for identification of those. 13 You know, I mean, the amount of literature, 14 and this is not just for talc, but for all of 15 these other, all of these other risk factors that 16 they look at, it is fairly, the amount is fairly 17 large, would be my guess, in terms of dietary 18 studies and those sorts of things. 19 So I can't imagine that they are on a monthly 20 basis reviewing absolutely everything. There is 21 no clarity here about what they are and are not 22 considering. 23 And the example of not having Phung in here 24 is, I think, a good example of that. You know, 25 why is Woolen, which was published in 2020, here</p>

25 (Pages 94 - 97)

<p style="text-align: right;">Page 98</p> <p>1 and Phung not. I don't know.</p> <p>2 Q You understand the NCI PDQ is not a document akin 3 to the litigation report that you offered that is 4 sixty pages or forty pages long?</p> <p>5 You understand that, correct?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 A I'm well aware that this document is really put 8 out for the general public versus litigation 9 versus the scientific community.</p> <p>10 Q And this version that we are looking at is a 11 version for health care professionals, correct?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A I believe it is. I believe they may have a 14 public-facing one, which is how -- yeah, go to the 15 patient version. So I'm clear on that. That 16 might be interesting to review.</p> <p>17 Again, this is not necessarily where 18 scientists go for the latest and the greatest data 19 or physicians even for that matter.</p> <p>20 Q Just the AACR?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 A No. We don't go to the AACR either.</p> <p>23 Q Only the AACR links to the PDQ.</p> <p>24 A Oh, they may, yes, for reasons unknown.</p> <p>25 Q And Karmanos links to the PDQ?</p>	<p style="text-align: right;">Page 100</p> <p>1 Do you see that?</p> <p>2 A I do.</p> <p>3 Q As you scroll through that, do you see any 4 reference to talc?</p> <p>5 A I do not.</p> <p>6 Q Do you think the WCRF is wrong not to list talc 7 here?</p> <p>8 MS. PARFITT: Objection to form.</p> <p>9 Q Yes or no?</p> <p>10 MS. PARFITT: Objection to form.</p> <p>11 A I believe that this is incomplete.</p> <p>12 Q Incomplete because talc is not listed?</p> <p>13 MS. PARFITT: Objection. Misstates her 14 testimony.</p> <p>15 A I believe that I am, as I stated with the NCI's, 16 I'm unaware how they did this review and how they 17 came to the conclusions and decided what to 18 include and what not to include.</p> <p>19 Q Finally, I know that you are currently in Indiana, 20 correct?</p> <p>21 A Yes.</p> <p>22 Q You were aware that Indiana is a member of the 23 NCCN?</p> <p>24 A They very recently became a member, yes.</p> <p>25 Q And that's a big deal?</p>
<p style="text-align: right;">Page 99</p> <p>1 A Correct. I believe they both do because this is a 2 source of national information, yes.</p> <p>3 But the methodology behind this is still not 4 clear.</p> <p>5 Q And I see from your C.V. that you are also 6 associated with the World Cancer Research Fund, 7 correct?</p> <p>8 A I have reviewed a grant for them once or twice in 9 the past.</p> <p>10 Q Are you aware that the World Cancer Research Fund 11 puts out a public-facing page for patients on 12 ovarian cancer?</p> <p>13 A I am not.</p> <p>14 Q I will mark this as Exhibit Number 10.</p> <p>15 (EXHIBIT NUMBER 10 WAS MARKED FOR 16 IDENTIFICATION.)</p> <p>17 Q Do you see the WCRF puts out a page titled Ovarian 18 Cancer, correct?</p> <p>19 A Correct.</p> <p>20 Q You can see here that they have a section on "What 21 causes ovarian cancer? Correct?</p> <p>22 A Correct.</p> <p>23 Q We see here there is, if you flip, there is one --</p> <p>24 flip over from the first to second page.</p> <p>25 There are also other causes.</p>	<p style="text-align: right;">Page 101</p> <p>1 MS. PARFITT: Objection to form.</p> <p>2 A The NCCN guidelines do direct really cancer 3 treatment and -- more so cancer treatment, but 4 also cancer diagnosis, yes.</p> <p>5 Q The NCCN is a respected cancer organization, 6 correct?</p> <p>7 A NCCN, yes. It's a network of multiple 8 organizations, yes.</p> <p>9 Q That is respected, correct?</p> <p>10 A For, yeah, for clinical purposes. Yes.</p> <p>11 Q Are you aware that the NCCN includes in its 12 guidelines a discussion of risk factors for 13 ovarian cancer?</p> <p>14 A I'm not aware of that, no.</p> <p>15 Q Are you aware that the NCCN guidelines currently 16 state that talc has not been conclusively 17 associated with ovarian cancer?</p> <p>18 A I'm not aware of that.</p> <p>19 MS. PARFITT: Objection.</p> <p>20 Q Would you disagree with the NCCN as well?</p> <p>21 MS. PARFITT: Objection to form.</p> <p>22 A Again, I don't know how the NCCN comes to this 23 sort of conclusion. If they have an actual, like 24 they do for treatment where they have a protocol 25 in place and they have, you know, clearly stated</p>

Page 102 1 methodology for what data they include and 2 exclude. 3 I don't know how the NCCN guidelines are for, 4 you know, something like risk factors how they 5 develop their opinions and their statements there. 6 So I really can't comment on it. 7 Q Have you talked with anybody at Indiana about talc 8 and ovarian cancer? 9 A Outside of the conflict of interest office, no. I 10 did let my, the people who work for me and with me 11 know where I was these last two days. 12 Q Have you talked with a gynecologic oncologist in 13 Indiana who is on the NCCN panel about talc and 14 ovarian cancer? 15 A No, I have not. 16 Q Do you know who she is? 17 A I can think of a couple. Is it Lisa Landrum? 18 Q I don't think so. I'm asking if you know. 19 A No. I'm not aware who the, who the GYN oncologist 20 at I.U. is who represents us, meaning I.U., on the 21 NCCN. 22 I'm fairly new to Indiana. My understanding 23 is Indiana is also recent, we are new to the NCCN 24 as well within the time that I have been there. 25 Q Does 2022 sound right?	Page 104 1 these. 2 Reviewed is perhaps a bit of a stronger 3 statement. 4 Q Let me see if I can short circuit this. 5 Are the materials that you intend to rely on 6 for your opinions in this litigation the materials 7 in your literature cited list? 8 A Correct. What I relied on is in the literature 9 cited list. 10 Q Are there any things listed on this additional 11 materials list that you intend to rely on or talk 12 to the jury about in offering your opinions in 13 this case? 14 MS. PARFITT: Objection to the form. 15 A So my understanding is between now and if this 16 does go to a jury trial I have the ability to 17 review more data, whether it's from peer reviewed 18 literature that is just newly published, whether 19 it's things that we request from you, like, you 20 know, defense documents. 21 As well as, I could go back to some of this 22 and rely on this for my testimony in court. That 23 is my understanding. 24 So potentially, yes, I may go back to some of 25 these, but I can't say. I mean, this is another
Page 103 1 A Yes. I started in September of 2022. 2 Q I will go back to your expert report. Okay? 3 A Okay. 4 Q We touched upon this earlier. Your report 5 includes a set of literature cited, correct? 6 A Correct. 7 Q Then a set of additional materials considered, 8 correct? 9 A I believe that the additional materials considered 10 is in a drop box. 11 Q Okay. Let me clarify here for you. 12 Let's go to your report and look at 13 Appendix B. That is toward the end of the packet. 14 A Yes. 15 Q So this list is different than your citations in 16 your report? 17 A Yes, that is correct. 18 Q Have you reviewed, and do you rely upon all of the 19 items listed on the Additional Materials 20 Considered list? 21 Let me split that in separate questions. 22 A Okay. 23 Q Have you reviewed all of the items listed on the 24 additional materials considered list? 25 A I believe I have at least had access to all of	Page 105 1 143 items. I can't say specifically which ones I 2 will pull out and rely on at a later date. 3 Q Okay. So just to tie that up. For purposes of 4 today, the opinions that you have to share with me 5 are based upon the literature cited list, is that 6 fair? 7 A In my report, yes. 8 Q As we sit here today, you have not formed any 9 additional opinions, you are not relying on these 10 additional materials considered, is that fair? 11 MS. PARFITT: Objection to the form. 12 A I believe that is fair, yes. 13 Q Okay. Then finally to really try to wrap this up, 14 in addition to the literature cited, the AMCL, 15 additional materials considered list, I believe 16 your counsel this morning referenced the fact that 17 a set of materials were shared with us via a drop 18 box. 19 Do you understand that to be true? 20 A I understand that to be true, yes. 21 Q Do you understand that that set of materials is 22 this AMCL set, or do you think that is a whole 23 other set? 24 A I believe it's what is listed here. 25 Q Okay.

27 (Pages 102 - 105)

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<p style="text-align: right;">Page 106</p> <p>1 A I've not cross referenced anything though.</p> <p>2 Q Understood.</p> <p>3 MS. PARFITT: It is eleven. Do we want to</p> <p>4 take a quick break?</p> <p>5 MR. JAMES: It has been another hour.</p> <p>6 Sure.</p> <p>7 (OFF RECORD AT 11:11 A.M.)</p> <p>8 AT THIS TIME A SHORT RECESS WAS HELD OFF</p> <p>9 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS</p> <p>10 WERE HAD:)</p> <p>11 (ON RECORD AT 11:19 A.M.)</p> <p>12 BY MR. JAMES:</p> <p>13 Q Dr. Cote, just to clarify a point earlier, in</p> <p>14 reference to a drop box of materials that has been</p> <p>15 shared with me, are you prepared today to offer</p> <p>16 any opinions on materials in that drop box that</p> <p>17 are not listed in your literature cited list?</p> <p>18 A No.</p> <p>19 Q If you do form additional opinions beyond what is</p> <p>20 disclosed today in your report, will you let your</p> <p>21 counsel know that?</p> <p>22 A Yes.</p> <p>23 MR. JAMES: And then you and I and others</p> <p>24 will have a discussion about what that means.</p> <p>25 Okay?</p>	<p style="text-align: right;">Page 108</p> <p>1 Q Are you an exposure scientist?</p> <p>2 A No.</p> <p>3 Q Are you a pathologist?</p> <p>4 A No. But I have long-term collaborations with</p> <p>5 pathologists and to the extent that, you know, my</p> <p>6 bachelor's of science was in biology, so I have</p> <p>7 had some exposure to some of the other fields you</p> <p>8 mentioned.</p> <p>9 As well as I spent a number of years with</p> <p>10 NIEHS, National Institute of Environmental Health</p> <p>11 Sciences funded center at Wayne State that focused</p> <p>12 on environmental health and toxicology issues.</p> <p>13 So I have had a lot of exposure to it</p> <p>14 throughout my career, but I don't define myself as</p> <p>15 that because I know true experts in that area.</p> <p>16 Q Do you have expertise in microscopy?</p> <p>17 A No.</p> <p>18 Q You are not a gynecologic pathologist either,</p> <p>19 correct?</p> <p>20 A Correct.</p> <p>21 Q Do you recognize gynecologic pathology as a</p> <p>22 special expertise of pathology?</p> <p>23 A Yes, I believe that that is a subspecialty. That</p> <p>24 is available at some, but not all, cancer centers,</p> <p>25 medical centers.</p>
<p style="text-align: right;">Page 107</p> <p>1 MS. PARFITT: Sure.</p> <p>2 MR. JAMES: For the record, that was</p> <p>3 directed towards Michelle.</p> <p>4 Q Were you ever a genetic counselor?</p> <p>5 A No.</p> <p>6 Q Do you have any expertise in mineralogy or mineral</p> <p>7 characterization?</p> <p>8 A No.</p> <p>9 Q Are you a mineral scientist?</p> <p>10 A No.</p> <p>11 Q Do you have any expertise in mineral analysis or</p> <p>12 testing?</p> <p>13 A No.</p> <p>14 Q Do you have any expertise in the testing for</p> <p>15 asbestos or talc?</p> <p>16 A No.</p> <p>17 Q Do you have any expertise in the various types of</p> <p>18 asbestos?</p> <p>19 A No.</p> <p>20 Q Do you have any expertise in geology or mining?</p> <p>21 A No.</p> <p>22 Q Are you a microscopist?</p> <p>23 A No.</p> <p>24 Q Are you a toxicologist?</p> <p>25 A No.</p>	<p style="text-align: right;">Page 109</p> <p>1 Q Have you ever talked with a gynecologic</p> <p>2 pathologist about the talc and ovarian cancer</p> <p>3 hypothesis?</p> <p>4 A No, I've not.</p> <p>5 Q Do you agree that for considering the relevant</p> <p>6 pathology evidence to the talc ovarian cancer</p> <p>7 hypothesis that the expertise of a gynecologic</p> <p>8 pathologist would be especially important?</p> <p>9 MS. PARFITT: Objection to form.</p> <p>10 A I'm not sure what you are meaning in terms of that</p> <p>11 they must have that subspecialty to be able to</p> <p>12 comment on literature on this case? I'm not sure</p> <p>13 what you are referring to.</p> <p>14 Can you rephrase the question?</p> <p>15 Q Have you reviewed any reports or opinions from a</p> <p>16 gynecologic pathologist on the issues in this</p> <p>17 case?</p> <p>18 A Not that I'm aware of, no. Reports would be</p> <p>19 individual level patient reports. And that I have</p> <p>20 not reviewed.</p> <p>21 As to whether some of the papers I reviewed</p> <p>22 had gynecologic oncologists on it, perhaps.</p> <p>23 Q Have you read any litigation reports from either</p> <p>24 side, plaintiffs or defense, from a gynecologic</p> <p>25 pathologist on the issues in this case?</p>

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<p style="text-align: right;">Page 110</p> <p>1 A No, not that I'm aware of. 2 Q You are not an oncologist, correct? 3 A Correct. I am not an oncologist. 4 Q You are not a cell biologist or cancer biologist, correct? 5 A I am not trained in cancer biology, no. But I 6 spent about twenty years in the cancer biology, it 7 was not a department, but we were a training 8 faculty for cancer biology students. 9 10 So I do feel like I have a good, but perhaps 11 not expert grasp of cancer biology. 12 Q And we talked earlier today about the in vitro 13 studies, correct? 14 A Correct. 15 Q And your testimony on that from this morning 16 remains? 17 A Correct. I do not do in vitro work in my own 18 laboratory. 19 Q Do you agree that prior to offering an expert 20 opinion on a particular topic that an expert 21 should be expected to conduct a comprehensive 22 review of the evidence on that topic? 23 MS. PARFITT: Objection. Form. 24 A Can you restate that question? 25 Q Sure. As a scientist like yourself,</p>	<p style="text-align: right;">Page 112</p> <p>1 A No, I did not do a comprehensive review on 2 fragrances or heavy metals. 3 Q Did you do a comprehensive review of the medical 4 and scientific literature on the alleged presence 5 of asbestos and related elements in talcum 6 powders? 7 MS. PARFITT: Objection. 8 A I did not do a review specifically of asbestos. I 9 certainly reviewed comprehensive reports by, for 10 example, IARC that included asbestos as their main 11 exposure of interest. 12 Q Just to be more precise, did you do a 13 comprehensive review of evidence related to the 14 alleged presence of asbestos in talcum powders? 15 A No, I did not do a comprehensive systematic 16 review. 17 Q Did you do a comprehensive review of the alleged 18 presence of fibrous talc in talcum powders? 19 MS. PARFITT: Objection. 20 A Again, I read a lot of literature about fibrous 21 talc. But I did not do a comprehensive systematic 22 review like I did for the epidemiologic studies. 23 Q And for the epidemiologic studies on talc and 24 ovarian cancer, correct? 25 A Yes. It was talc as a whole. It was not the</p>
<p style="text-align: right;">Page 111</p> <p>1 methodologically before offering an opinion on a 2 specific topic, do you agree that you should do a 3 comprehensive review of the medical and scientific 4 literature on that topic? 5 A I agree that a comprehensive review should be 6 undertaken before entering an opinion, yes. 7 Q For purposes of the report and your opinions in 8 this litigation, did you do a comprehensive review 9 for medical and scientific evidence on the alleged 10 presence of heavy metals in talc powders? 11 A I did not do a systematic review of heavy metal in 12 talc powder. 13 Q And related to that, did you do a systematic or a 14 comprehensive review on the alleged 15 carcinogenicity of heavy metals in talcum powders? 16 A No, I did not do a systematic review. 17 Q Did you do a comprehensive review on the alleged 18 relationship between heavy metals and ovarian 19 cancer? 20 A No, I did not do a comprehensive systematic review 21 regarding heavy metals and ovarian cancer. 22 Q Did you do a comprehensive review for medical or 23 scientific evidence on the alleged presence or 24 carcinogenicity of chemicals in talcum powder 25 fragrances?</p>	<p style="text-align: right;">Page 113</p> <p>1 components. It was whatever was in the bottles or 2 containers of talc that the women were using. 3 Q Did you do a comprehensive review of the actual 4 underlying articles on the alleged association or 5 relationship between asbestos and ovarian cancer? 6 MS. PARFITT: Objection. Form. 7 A No, I did not do my own individual review of the 8 articles going back to the literature. 9 For example, like what was cited in IARC, for 10 example, I did not do that. 11 Q I understand from your report you looked at IARC 12 2012, correct? 13 A There were two others as well. 14 Q Understood. For purposes of asbestos you are 15 referring to having reviewed IARC 2012, is that 16 right? 17 MS. PARFITT: Objection. Objection. 18 MR. JAMES: I will just withdraw the 19 question. 20 Q Before being retained in the litigation what was 21 your opinion on the relationship between talc and 22 ovarian cancer? 23 A Before being retained? So based on the paper that 24 we published in 2016, which I, myself, at that 25 time did not perform a systematic review, but it</p>

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<p>Page 114</p> <p>1 was certainly included as, you know, the more 2 primary authors of that paper, Schildkraut and 3 probably Moorman. I'm not recalling who the 4 second author on the paper was, but those are 5 usually kind of the three who do the first draft 6 and a lot more of the heavy lifting.</p> <p>7 I felt like based on the epidemiologic 8 evidence that there was a consistent association. 9 And by consistency I mean the point estimates for, 10 you know, the different -- here it was mostly case 11 control studies at the time -- were consistent 12 across multiple populations over the last, you 13 know, thirty or forty decades across the globe. 14 So I felt like there was really strong 15 epidemiologic evidence that suggested an 16 association.</p> <p>17 In terms of causation, I didn't form any real 18 opinion of causation until I started this work, 19 like, in late fall of this year.</p> <p>20 Q Okay. Given that, then prior to your involvement 21 in this litigation, is it correct that you have 22 not expressed publicly or to professional 23 colleagues that you consider talc to be a cause of 24 ovarian cancer?</p> <p>25 MS. PARFITT: Objection. Form.</p>	<p>Page 116</p> <p>1 done a systematic review -- that asbestos has been 2 named as a Group 1 carcinogen by IARC for well 3 over a decade now. I think that there is evidence 4 that also points towards talcum powder contains 5 asbestos or fibrous talc, and that could be a 6 causal agent for ovarian cancer. Yes.</p> <p>7 Q Again, you agree you did not systematically or 8 comprehensively look at the evidence on the 9 presence of asbestos in talcum powders, correct?</p> <p>10 MS. PARFITT: Objection. Asked and 11 answered.</p> <p>12 Q Is that correct?</p> <p>13 A I did not do a systematic review specifically 14 looking at asbestos and the association with 15 ovarian cancer.</p> <p>16 Q On Page 11 of your report, can you turn to it?</p> <p>17 A Yes.</p> <p>18 Q Under the Other Substances subheading in the 19 second sentence you say, "In addition to platy 20 talc, talcum powder often contains asbestos and 21 almost always contains talc fibers."</p> <p>22 Do you see that?</p> <p>23 A Yes. Correct.</p> <p>24 Q Did you do a systematic review to support that 25 opinion?</p>
<p>Page 115</p> <p>1 A Correct. There would be no place that I ever 2 would have stated that talc is a cause of ovarian 3 cancer.</p> <p>4 I mean, my work, my published work states 5 that we believe that there is an association. But 6 that is different than cause.</p> <p>7 Q And in the Schildkraut paper, which we will look 8 at, I believe that I saw the term suggestive of an 9 association.</p> <p>10 Does that sound accurate to you?</p> <p>11 MS. PARFITT: Objection. Form.</p> <p>12 A I don't recall how it was classified in that 13 paper.</p> <p>14 Q Fair enough.</p> <p>15 A We can wait until later.</p> <p>16 Q Fair enough.</p> <p>17 A Okay.</p> <p>18 Q Given your testimony on what you have and have not 19 comprehensively looked at, in this case do you 20 intend to offer an expert opinion that talcum 21 powders are contaminated with asbestos?</p> <p>22 MS. PARFITT: Objection to the form.</p> <p>23 You may answer.</p> <p>24 A Based on what I have seen provided, I would give 25 an opinion that -- recognizing that I have not</p>	<p>Page 117</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 A No. That opinion was supported by the Longo and 3 Rigler historical samples that I cited right in 4 the next sentence.</p> <p>5 Q And that is all it's supported by, correct?</p> <p>6 MS. PARFITT: Objection.</p> <p>7 A I think that is also supported by the next 8 sentence that says, "Internal testing by Johnson & 9 Johnson with testing done sporadically from 1957 10 to 1992 showed various samples contained asbestos 11 and/or talc fibers."</p> <p>12 That one is also referenced.</p> <p>13 And then the third line of evidence that I 14 have there is that, "As recently as October 18, 15 2019, the FDA updated a Safety Alert and issued a 16 Constituent Update warning consumers not to use 17 certain cosmetic products that tested positive for 18 asbestos, after a sample of Johnson's Baby Powder 19 tested positive for asbestos and talc fibers."</p> <p>20 They give the lot number.</p> <p>21 Q Doctor --</p> <p>22 A Then the final piece of evidence that supported 23 that first sentence was from, "The Final Rule from 24 the Environmental Protection Agency of the 25 'Asbestos; Reporting and Recordkeeping'</p>

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<p style="text-align: right;">Page 118</p> <p>1 Requirements Under the Toxic Substances Control 2 Act', published July 25, 2023, recognizes the 3 co-occurrence of asbestos and talc as such: 'EPA 4 maintains that talc and vermiculite are some 5 examples of the bulk commodities that may contain 6 asbestos as an impurity."</p> <p>7 So, you know, I think I use there if I'm 8 counting correctly, one, two, three, four 9 different sources from very different 10 organizations or people.</p> <p>11 Q Does the EPA document that you cite support the 12 proposition that talcum powders often contain 13 asbestos? Yes or no?</p> <p>14 A I don't know. I would have look at that full 15 document. I have just quoted that they maintain 16 that talc and vermiculite are some examples of 17 bulk commodities that may contain asbestos.</p> <p>18 Q Does even that sentence talk about talcum powders? 19 It talks about talc as a bulk commodity, 20 correct?</p> <p>21 A It does, yes.</p> <p>22 Q The FDA letter, do you understand that the FDA 23 testing you cite pertains to a single bottle, 24 correct?</p> <p>25 MS. PARFITT: Objection. Form.</p>	<p style="text-align: right;">Page 120</p> <p>1 results of talcum powder products from 1957 to 2 1992?</p> <p>3 MS. PARFITT: Objection to the form of the 4 question.</p> <p>5 A I have no idea what types of internal testing was 6 done outside of what I saw in that report.</p> <p>7 Q As a scientist are you intending to offer an 8 opinion that talcum powders often contain 9 asbestos?</p> <p>10 Is that an opinion that you are intending to 11 offer?</p> <p>12 And are these the lines of evidence that you 13 intend to cite to support that?</p> <p>14 MS. PARFITT: Objection. Asked and 15 answered.</p> <p>16 A I intend to state what I have listed here in my 17 expert report, that there have been various 18 individuals and agencies who have found at various 19 points in time over the last five decades, 20 including the FDA, that there is asbestos and/or 21 talc fibers contained in talcum powder.</p> <p>22 Q And I'm focused on the word "often." You are the 23 one in your expert report using the word "often." 24 Do you see that?</p> <p>25 A Yes.</p>
<p style="text-align: right;">Page 119</p> <p>1 You may answer.</p> <p>2 A Correct. But my understanding is that the FDA 3 does not test every single bottle. It tests a 4 subset.</p> <p>5 Q But does the FDA testing support the proposition 6 that talcum powder often contains asbestos? Yes 7 or no?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 A I do not know.</p> <p>10 Q The internal testing says in your sentence that 11 testing was done sporadically.</p> <p>12 Does the internal testing support the opinion 13 that talcum powder often contains asbestos?</p> <p>14 A I would have to go back to that. That is the 15 Hopkins document, I believe.</p> <p>16 Q Did you look at any actual testing documents?</p> <p>17 A I looked at a spreadsheet.</p> <p>18 Q A spreadsheet?</p> <p>19 A Yes.</p> <p>20 Q Did you look at actual testing results?</p> <p>21 A Can you clarify? I am not sure what you are 22 meaning by that.</p> <p>23 My understanding looking at that spreadsheet 24 was that those were the actual testing results.</p> <p>25 Q Do you think that is the sum total of the testing</p>	<p style="text-align: right;">Page 121</p> <p>1 Q Do you have a quantitative judgment --</p> <p>2 A Yes.</p> <p>3 Q -- that talcum powders often contain asbestos? Is 4 that your opinion?</p> <p>5 MS. PARFITT: Asked and answered.</p> <p>6 A Based on data that has, you know, we have been 7 found or has been provided, yes, I stand by often.</p> <p>8 And that right here is based on Longo and 9 Rigler stating that sixty-eight percent of the 10 samples contained asbestos and ninety-eight 11 percent of the samples contained fibrous talc.</p> <p>12 I would consider that often.</p> <p>13 Q You would agree you don't have any expertise in 14 mineralogy or testing for asbestos, correct?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 A I would agree I don't have that expertise, but I 17 can read a lab report.</p> <p>18 Q You can read?</p> <p>19 A Yes.</p> <p>20 Q The jury can read, correct?</p> <p>21 MS. PARFITT: Argumentative.</p> <p>22 If you have a question, ask it.</p> <p>23 Q Can the jury read?</p> <p>24 MS. PARFITT: Objection to that question.</p> <p>25 A It's impossible to answer. I don't know who the</p>

<p style="text-align: right;">Page 122</p> <p>1 jury is. I will probably not administer a reading 2 test to them.</p> <p>3 Q The Longo report that you cite is a litigation 4 byproduct, correct?</p> <p>5 MS. PARFITT: Objection to form.</p> <p>6 A It's my understanding that, yes, it's a litigation 7 byproduct?</p> <p>8 Q And did you request access to Longo's testing?</p> <p>9 A Yes, I believe I did.</p> <p>10 Q Did you read the entirety of Longo's report?</p> <p>11 A I scanned the entirety of that report, yes. I 12 mean, it's the MAC report. That is the name of 13 the company, I believe, that they work under.</p> <p>14 Q Have you reviewed all of Longo's publications and 15 testing on talcum powders, or is this all you have 16 reviewed from Longo?</p> <p>17 MS. PARFITT: Objection to the question. 18 I'm not sure I know what you are asking.</p> <p>19 MR. JAMES: I think you know. That is 20 fine.</p> <p>21 Q Is this all you have reviewed from Longo?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 A Yes, this is what I have reviewed from Longo.</p> <p>24 Q And is this part of the published medical 25 literature?</p>	<p style="text-align: right;">Page 124</p> <p>1 testing done by Johnson & Johnson.</p> <p>2 Q That was -- sorry.</p> <p>3 A That was my understanding of what Johnson & 4 Johnson had to offer. I am not aware of any other 5 materials, but I'm happy to review them.</p> <p>6 Q And that was the spreadsheet selected for you by 7 plaintiff's counsel?</p> <p>8 MS. PARFITT: Objection to form.</p> <p>9 A The spreadsheet was provided to me by counsel.</p> <p>10 A Yes.</p> <p>11 Q Do you know that there have been thousands of 12 testing and testing documents done since the 13 timeframe that you cite?</p> <p>14 MS. PARFITT: Objection to form.</p> <p>15 Q Here you refer to the 1950s.</p> <p>16 A Are you aware that there have been thousands 17 of tests performed on talcum powders during that 18 time period?</p> <p>19 MS. PARFITT: Objection to form.</p> <p>20 A I'm not aware of that. I'm aware of another that 21 I list here in my report. If you want to go back 22 to my expert testimony to that second paragraph, 23 it was a study done in Malaysia by Almugren.</p> <p>24 They tested four different types of talcum 25 powder products currently available. One was</p>
<p style="text-align: right;">Page 123</p> <p>1 MS. PARFITT: Objection.</p> <p>2 A I don't believe it is.</p> <p>3 Q Is this peer reviewed?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 A I'm unaware if they have peer reviewed any of 6 this.</p> <p>7 Q Had you ever heard of Longo or Rigler before you 8 became a litigation expert?</p> <p>9 A No.</p> <p>10 Q Do you know how many times they have testified for 11 plaintiffs in the talc litigation?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A No, I have no knowledge of that.</p> <p>14 Q Do you know how much money they have earned as 15 experts in the talc litigation?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 A I have no idea how much money they have earned.</p> <p>18 Q Do you know if their opinions have ever been 19 excluded by a court as unreliable?</p> <p>20 MS. PARFITT: Objection to form.</p> <p>21 A I have no idea of their opinions, no.</p> <p>22 Q Did you ask if defendants have provided any 23 contrary evidence to Longo and Rigler?</p> <p>24 A No, I really looked at the defendant evidence as 25 the stuff, the Hopkins report that was internal</p>	<p style="text-align: right;">Page 125</p> <p>1 Johnson's Baby Powder. They noted that all of 2 them contained nickel, arsenic, and lead. They 3 also talked about, you know, the prior studies in 4 this area.</p> <p>5 So there is -- I'm aware that there has been 6 other testing done. I don't have it at my 7 fingertips in terms of the thousands of documents 8 you have been talking about.</p> <p>9 I'm aware there has been further testing done 10 looking at different constituents of Johnson's 11 Baby Powder.</p> <p>12 Q As a scientist if you are going to make a comment 13 on a topic like talcum powders often contained 14 asbestos, as a scientist don't you think it's 15 important to look at the material and the evidence 16 and the testimony and the documents relevant to 17 that claim?</p> <p>18 MS. PARFITT: Objection. Misstates her 19 testimony.</p> <p>20 You can answer.</p> <p>21 A As a scientist, I cited four different sources 22 that all had the same conclusion that they had 23 found evidence at some point of asbestos and/or 24 fibrous talc in the product.</p> <p>25 It was four. It was Longo and Rigler. It</p>

32 (Pages 122 - 125)

<p style="text-align: right;">Page 126</p> <p>1 was Hopkins. It was the FDA. And it was kind of 2 the final ruling of the EPA.</p> <p>3 Q Okay.</p> <p>4 A To me that is four distinct pieces of evidence. 5 Recognizing that I did not do a systematic review 6 and that this was not to build causation, this was 7 just to look at biologic plausibility, I feel like 8 it was a sufficient read.</p> <p>9 Q Did you look at any other FDA testing? 10 Do you know if the FDA has tested any other 11 talcum powders?</p> <p>12 MS. PARFITT: Objection to form.</p> <p>13 A I have not looked at other talcum powders. I 14 really just considered talcum powder as a whole.</p> <p>15 Q I appreciate that. Again, you have in your expert 16 report the sentence that talcum powder often 17 contains asbestos.</p> <p>18 I have asked you if you intend to offer that 19 opinion. You are telling me yes. That is why I'm 20 asking what you have relied on.</p> <p>21 So the sum total of what you have relied on 22 to support that statement as a scientist is 23 contained in this paragraph, is that correct?</p> <p>24 MS. PARFITT: Objection. Misstates her 25 testimony. I think she just talked to you about</p>	<p style="text-align: right;">Page 128</p> <p>1 on asbestos testing? 2 A No.</p> <p>3 MS. PARFITT: Objection.</p> <p>4 A No, I have not.</p> <p>5 Q Have you reviewed any documents that give context 6 to the entries on the spreadsheet that you 7 reviewed?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 A No, I have not. But I have reserved my right to 10 review more after this deposition.</p> <p>11 Q Did you look for any published literature on the 12 claim that talcum powders have asbestos in them?</p> <p>13 A I'm sorry. Can you repeat that?</p> <p>14 Q Sure. I'm sorry.</p> <p>15 Did you comprehensively look for published 16 literature on the topic of the presence of 17 asbestos in talcum powders?</p> <p>18 A No. That would be looking at a systematic review 19 of the components of talcum powder and I did not 20 do that.</p> <p>21 Q Do you have any familiarity of the specifications 22 for talcum powder products?</p> <p>23 MS. PARFITT: Objection to form.</p> <p>24 A No. I'm unaware of what the specifications are. 25 I assume you mean like purity or something along</p>
<p style="text-align: right;">Page 127</p> <p>1 the EPA as well.</p> <p>2 MR. JAMES: That is in the paragraph.</p> <p>3 MS. PARFITT: The recent EPA.</p> <p>4 A What was the question?</p> <p>5 Q You are just parroting Dr. Longo's conclusion, 6 correct?</p> <p>7 MS. PARFITT: Scott, you are being 8 argumentative and borderline disrespectful to Dr. 9 Cote. That is not your nature, so I would ask 10 that you stop.</p> <p>11 MR. JAMES: I disagree with you. I'm 12 entitled to ask questions about this report.</p> <p>13 Q Dr. Cote, with all due respect --</p> <p>14 MS. PARFITT: Thank you.</p> <p>15 Q -- you were citing in this paragraph the sources 16 that you were relying on for the opinion that 17 talcum powder often contains asbestos, is that 18 correct?</p> <p>19 A That is the opinion put forth and supported by 20 four different references.</p> <p>21 Q Did you review Dr. Hopkins' testimony about the 22 spreadsheet that you were given?</p> <p>23 A I did not.</p> <p>24 Q Have you reviewed any testing or expert reports 25 from Johnson & Johnson experts in this litigation</p>	<p style="text-align: right;">Page 129</p> <p>1 those lines? No, I'm not aware of what those are.</p> <p>2 Q Are you aware that talcum powders are produced in 3 accordance with standards set by the USP?</p> <p>4 Is that a body that you have ever heard of?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 A I believe I'm familiar with the USP as a body.</p> <p>7 What their actual charge is I'm less clear.</p> <p>8 Q Do you have any familiarity with USP in 9 relationship to talcum powders?</p> <p>10 A No, I do not.</p> <p>11 Q Did you look at the FDA testing in 2010 of talcum 12 powders?</p> <p>13 A I did not look at the testing in 2010.</p> <p>14 Q Do you understand that the FDA has recognized that 15 large deposits of high purity asbestos free talc 16 exists geologically?</p> <p>17 Were you aware of that?</p> <p>18 MS. PARFITT: Objection to form.</p> <p>19 A I have not examined where high purity talc exists 20 and whether or not the FDA has made statements 21 towards this.</p> <p>22 Q Do you have any familiarity with where Johnson & 23 Johnson sources its talcum powders from?</p> <p>24 A I believe that has changed over time.</p> <p>25 Q Do you have any familiarity with the geology of</p>

<p style="text-align: right;">Page 130</p> <p>1 those areas?</p> <p>2 A No. I believe currently that China is where much</p> <p>3 of it is sourced. That is a very large country</p> <p>4 that I have never visited. So I'm unaware of the</p> <p>5 geology.</p> <p>6 Q Do you have any opinions on the amount of alleged</p> <p>7 asbestos in Johnson & Johnson's finished products?</p> <p>8 A I am unaware of the amount of asbestos in Johnson</p> <p>9 & Johnson's finished products.</p> <p>10 But I would assume that any amount of</p> <p>11 asbestos is potentially carcinogenic.</p> <p>12 Q Do you have any expertise in exposure to asbestos</p> <p>13 in ambient air?</p> <p>14 Is that something that you have ever looked</p> <p>15 at?</p> <p>16 A No. I have not studied ambient air and asbestos</p> <p>17 exposure.</p> <p>18 Q Do you have any expertise in exposures to asbestos</p> <p>19 through other everyday life activities?</p> <p>20 A No. I'm not aware. Although, I know asbestos is</p> <p>21 ubiquitous. It's almost everywhere.</p> <p>22 Q If there isn't asbestos in Johnson & Johnson</p> <p>23 talcum powders do you still hold the opinion that</p> <p>24 talcum powders are a general cause of ovarian</p> <p>25 cancer?</p>	<p style="text-align: right;">Page 132</p> <p>1 an epidemiologic standpoint where people who are</p> <p>2 using talcum powder of whatever brand or whatever</p> <p>3 type, they don't know what is in that bottle.</p> <p>4 So when I am reviewing it, I'm reviewing talc</p> <p>5 and everything that it contains. But the</p> <p>6 assumption is that there is not asbestos in that</p> <p>7 talc.</p> <p>8 But the review is everything that is</p> <p>9 contained in that talc bottle.</p> <p>10 Q The body of literature on talcum powders and</p> <p>11 ovarian cancer tests the hypothesis whatever is it</p> <p>12 in?</p> <p>13 A Yes.</p> <p>14 Q Is that fair?</p> <p>15 A All of the constituents that are in talc -- that</p> <p>16 are in the bottle, let's just say, because they</p> <p>17 might be co-occurring with it. It might be</p> <p>18 something that is intentionally added like</p> <p>19 fragrances.</p> <p>20 It's everything within that bottle with talc</p> <p>21 being the primary component.</p> <p>22 Q Have you ever conducted, outside of litigation, a</p> <p>23 comprehensive review on the literature of asbestos</p> <p>24 and ovarian cancer?</p> <p>25 MS. PARFITT: Objection. The question was</p>
<p style="text-align: right;">Page 131</p> <p>1 A Yes, I do.</p> <p>2 Q Does it change your opinions in any way?</p> <p>3 A No, it does not. When I started with, you know,</p> <p>4 my initial assumption in the report that I built</p> <p>5 on was that these were not asbestos containing.</p> <p>6 So the conclusions in the report are with the</p> <p>7 assumption, despite what I think was some evidence</p> <p>8 that was kind of revealed as I reviewed, but the</p> <p>9 assumption in my conclusions are that it is talcum</p> <p>10 powder that is free of asbestos.</p> <p>11 Q Okay. I saw that. Let me clarify that.</p> <p>12 A Okay.</p> <p>13 Q Are your opinions predicated on the assumption</p> <p>14 that talcum powders are asbestos free?</p> <p>15 MS. PARFITT: Objection. Form. Misstates</p> <p>16 the testimony.</p> <p>17 A Yeah. Can you rephrase that?</p> <p>18 Q I'm asking you to tell me. Right.</p> <p>19 I think you just used the word "assumed." I</p> <p>20 saw that at one point in your report.</p> <p>21 Are you offering your opinions based on the</p> <p>22 assumption that talcum powders are asbestos free?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 Q You tell me.</p> <p>25 A So when I reviewed this and, again, this is from</p>	<p style="text-align: right;">Page 133</p> <p>1 asked and answered.</p> <p>2 A No. I have never done a systematic review of</p> <p>3 asbestos and ovarian cancer.</p> <p>4 Q Sitting here today, do you have the opinion that</p> <p>5 asbestos is an established cause of ovarian</p> <p>6 cancer?</p> <p>7 A So I did not do a causal analysis -- or I'm</p> <p>8 sorry -- a systematic review with a causal</p> <p>9 analysis for asbestos and ovarian cancer.</p> <p>10 I did it for talcum powder and specifically</p> <p>11 perineal use or genital use of talcum powder and</p> <p>12 ovarian cancer.</p> <p>13 Q With respect to fibrous talc, you comment on that</p> <p>14 in your report, correct?</p> <p>15 A Yes.</p> <p>16 Q In your mind, do you distinguish fibrous talc from</p> <p>17 asbestos talc?</p> <p>18 Are those two things the same or are those</p> <p>19 two things different?</p> <p>20 A Yes, I believe that fibrous talc, and this is</p> <p>21 coming right from Page 11, The Exposure: Talc.</p> <p>22 I say, you know, that talc is usually platy.</p> <p>23 It grows in sheets or plates. So it's really just</p> <p>24 about the formation. But may also occur as</p> <p>25 asbestos fibers or fibrous talc.</p>

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<p style="text-align: right;">Page 134</p> <p>1 That asbestiform refers to the pattern of the 2 growth, which is not to be confused with talc that 3 separately contains asbestos.</p> <p>4 Q And I did read your report.</p> <p>5 A Okay.</p> <p>6 Q What I'm trying to grapple with is your use of the 7 terminology.</p> <p>8 A Yes.</p> <p>9 Q Okay. Do you think fibrous talc and asbestiform 10 talc, are those two terms interchangeable in your 11 mind?</p> <p>12 A That is how I interpret it, yes. It has very 13 little to do -- again, ultimately, I'm looking at 14 talc and all it contains is what the basis of the 15 report is built on.</p> <p>16 Q Do you think fibrous talc, the term fibrous talc, 17 and the term talc containing asbestiform fibers, 18 are they in your mind interchangeable?</p> <p>19 Do they mean the same thing?</p> <p>20 A Yes.</p> <p>21 Q That is your understanding?</p> <p>22 A That those are two equivalent terms.</p> <p>23 Q To wrap this up, you use the term fibrous talc, 24 the term asbestiform talc, and the term talc 25 containing asbestos fibers interchangeably?</p>	<p style="text-align: right;">Page 136</p> <p>1 Q Then also in this sentence you would say talc 2 fibers are also interchangeable, correct?</p> <p>3 A Yes.</p> <p>4 Q You cite the IARC Monograph from 2012 for the 5 proposition that the term fibrous talc is 6 classified by IARC as a Class 1 human carcinogen, 7 do you see that?</p> <p>8 A I'm not sure I do. Can you point to where that 9 is?</p> <p>10 Q Yes. In the same paragraph about halfway up. 11 "Talc may also form fibers..."</p> <p>12 Do you see that?</p> <p>13 A Yes.</p> <p>14 Q Five lines up.</p> <p>15 A Yes.</p> <p>16 Q The next sentence says, "This type of talc, 17 referred to as fibrous talc..."</p> <p>18 A It says, "Talc may also form fibers that are 19 asbestiform in habit, meaning they have greater 20 strength, flexibility and durability. This type 21 of talc, referred to as fibrous talc, has also 22 been classified by IARC as a Class 1 human 23 carcinogen."</p> <p>24 So, yes, talc with fibers that are 25 asbestiform in habit is referred to as fibrous</p>
<p style="text-align: right;">Page 135</p> <p>1 A I'm not sure where I put each of those 2 interchangeably in the report. I tended to -- if 3 I referred to them, I referred to them as the 4 authors of whatever literature referred to them.</p> <p>5 But, yes, the asbestiform fibers is the same 6 as fibrous talc. And what was the third one?</p> <p>7 Q Talc containing asbestiform fibers.</p> <p>8 A Talc containing asbestos fibers. I don't know if 9 I used that in the report. I would have to see 10 how I referred to that.</p> <p>11 But the first two, the asbestiform fibers and 12 fibrous talc are interchangeable to me.</p> <p>13 Q On Page 16, in the second paragraph at the end of 14 that paragraph you say, "Therefore, both talc 15 containing asbestiform fibers (i.e., talc fibers) 16 and talc containing asbestos should be considered 17 carcinogenic..."</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q That is where I pulled that term from.</p> <p>21 A That was from the IARC Monograph.</p> <p>22 Q You believe asbestiform talc, fibrous talc, and 23 talc containing asbestos fibers are the same 24 thing?</p> <p>25 A I think, yes.</p>	<p style="text-align: right;">Page 137</p> <p>1 talc based on this statement. And they are both 2 Class 1 carcinogens.</p> <p>3 Q Sitting here today, do you know if the term 4 "fibrous talc" is used anywhere in the IARC 5 Monograph?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 A Sitting here today, no, I do not know how they 8 refer to it.</p> <p>9 Q Would it surprise you to learn that the term 10 "fibrous talc" is actually not contained in the 11 2012 Monogram?</p> <p>12 MS. PARFITT: Objection to form.</p> <p>13 A I'm not surprised by much of anything. So, no, it 14 would not surprise me.</p> <p>15 Q Do you have any familiarity with the term cleavage 16 fragment?</p> <p>17 A With respect to DNA analysis, that is my primary 18 go to, yes.</p> <p>19 Q Understood. Do you have any familiarity with that 20 term of art used in the context of mineralogy?</p> <p>21 A No, I do not.</p> <p>22 Q With respect to heavy metals, earlier today you 23 mentioned the Almugren article, correct?</p> <p>24 A Yes.</p> <p>25 Q You also cite in your report the presence of heavy</p>

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<p style="text-align: right;">Page 138</p> <p>1 metals, the Pier deposition?</p> <p>2 A Correct.</p> <p>3 Q Are there any other materials that you rely on for</p> <p>4 the presence of heavy metals in talcum powders?</p> <p>5 A No, I did not do a systematic review of talcum</p> <p>6 powder and heavy metals.</p> <p>7 Q Was the Pier deposition given to you by counsel?</p> <p>8 A Yes, it was.</p> <p>9 Q And was the Almugren article given to you by</p> <p>10 counsel?</p> <p>11 A No.</p> <p>12 Q Okay. Was that something that you found on your</p> <p>13 own?</p> <p>14 A Yes.</p> <p>15 Q Did you read the entirety of the Pier deposition</p> <p>16 or just sections?</p> <p>17 A I did not read the entirety of it.</p> <p>18 Q And did you read sections pertaining to heavy</p> <p>19 metals?</p> <p>20 A Yes.</p> <p>21 Q Were those sections selected for you?</p> <p>22 A No, they were not.</p> <p>23 Q Did you ask for the Pier deposition?</p> <p>24 A I asked for materials related to other components</p> <p>25 or other things found.</p>	<p style="text-align: right;">Page 140</p> <p>1 expertise is.</p> <p>2 Q I was not meaning to suggest the broader topic.</p> <p>3 This was specific to heavy metals.</p> <p>4 A Correct.</p> <p>5 Q You have reviewed a very limited set of materials,</p> <p>6 fair?</p> <p>7 MS. PARFITT: Objection to form.</p> <p>8 A Yes, I did not do a comprehensive review or</p> <p>9 systematic review of heavy metals.</p> <p>10 Q Just like with asbestos, you didn't look at any</p> <p>11 testing document on heavy metals?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A From what was in Pier, yes. Other than that, no.</p> <p>14 Q Other than Pier, you have not looked at any</p> <p>15 testing document from Johnson & Johnson or the</p> <p>16 defendants, correct?</p> <p>17 MS. PARFITT: Objection.</p> <p>18 A Correct. That was not the focus of this report at</p> <p>19 all.</p> <p>20 Q And are you aware there are specifications</p> <p>21 relevant to the presence of heavy metals in talcum</p> <p>22 powders?</p> <p>23 MS. PARFITT: Objection. Vague.</p> <p>24 A I'm aware that there are probably some sort of</p> <p>25 standards or regulations in place for most</p>
<p style="text-align: right;">Page 139</p> <p>1 Q You have the Pier deposition, correct?</p> <p>2 A Yes.</p> <p>3 Q Did you get any other materials?</p> <p>4 Did you get testimony or reports from Johnson</p> <p>5 & Johnson witnesses?</p> <p>6 A No, I do not believe I have.</p> <p>7 Q Did you get any materials or testimony or</p> <p>8 documents from Johnson & Johnson experts on the</p> <p>9 issue of heavy metals in talcum powders?</p> <p>10 A No. I do not believe I asked for any of that.</p> <p>11 That was really not the focus of my report.</p> <p>12 Again, this is here for completeness' sake to</p> <p>13 recognize that there are other components that are</p> <p>14 in these sorts of talcum powders. Whether they</p> <p>15 kind of co-occur naturally or whether they are</p> <p>16 added afterwards for, for example, fragrance, it's</p> <p>17 really just to describe in a more comprehensive</p> <p>18 manner that there are other agents found within</p> <p>19 these bottles of talc.</p> <p>20 Q Based on the limited set of materials that you</p> <p>21 have reviewed, correct?</p> <p>22 MS. PARFITT: Objection to that question.</p> <p>23 A I actually feel like I have reviewed a very large</p> <p>24 amount of literature in this area. But it was</p> <p>25 focused on epidemiologic, which is where my</p>	<p style="text-align: right;">Page 141</p> <p>1 cosmetic items.</p> <p>2 Q You did not review the specifications, is that</p> <p>3 fair?</p> <p>4 A Fair. No.</p> <p>5 Q Do you know if the talcum powders in the Almugren</p> <p>6 article are distributed in the United States?</p> <p>7 Do you know if they were?</p> <p>8 A I am unaware as to where they were distributed.</p> <p>9 Q Did you see that the article made reference to</p> <p>10 Malaysia?</p> <p>11 A Yes. That is stated in the report.</p> <p>12 They were products currently available in</p> <p>13 Malaysia.</p> <p>14 Q Did you review any IARC Monograph asserting that</p> <p>15 the presence of heavy metals in talcum powders</p> <p>16 renders those powders carcinogenic?</p> <p>17 A I would have to look at the IARC documents that I</p> <p>18 reviewed. I believe that they do have, they do</p> <p>19 have -- the first one is looking at arsenic,</p> <p>20 metals, fibers, and dust. I say first one. That</p> <p>21 is the 2012 one. That is the first one I</p> <p>22 discussed after the Health Canada report on</p> <p>23 Page 16.</p> <p>24 Q Just sitting here today, do you know if that</p> <p>25 monograph includes the claim that the presence of</p>

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<p style="text-align: right;">Page 142</p> <p>1 heavy metals renders talcum powders carcinogenic?</p> <p>2 Do you know sitting here?</p> <p>3 MS. PARFITT: Objection to form.</p> <p>4 A Sitting here right now off the top of my head, no.</p> <p>5 We can look at that because we have the</p> <p>6 documentation here.</p> <p>7 Q I didn't see in your report a claim that the IARC</p> <p>8 Monograph supported the notion that heavy metals</p> <p>9 in powders renders powders carcinogenic.</p> <p>10 Did you make that claim in your report?</p> <p>11 MS. PARFITT: Objection to the form.</p> <p>12 A I don't make that claim in the report. I would</p> <p>13 say I do note in here that the report, meaning the</p> <p>14 one published in 2012, focused on Group 1</p> <p>15 carcinogens. Those that are viewed to be</p> <p>16 carcinogenic in humans. That included arsenic,</p> <p>17 fibers, metals, and dust.</p> <p>18 Q That is also what you talked about earlier with</p> <p>19 regard to asbestos, correct?</p> <p>20 That is the monograph you looked at on</p> <p>21 asbestos, correct?</p> <p>22 A It was that one, but it was also the 2010. And</p> <p>23 then there was an earlier one as well.</p> <p>24 Q Okay. Are you aware of any study substantiating</p> <p>25 the theory that trace amounts of heavy metals</p>	<p style="text-align: right;">Page 144</p> <p>1 fragrances or fragrance chemicals?</p> <p>2 MS. PARFITT: Objection to form.</p> <p>3 A No, I am unaware how the fragrances were tested</p> <p>4 for.</p> <p>5 Again, almost anybody with a nose can smell</p> <p>6 that they are highly fragranced products.</p> <p>7 Q Did you ask for the Crowley report?</p> <p>8 A Not specifically. I asked for reports that may</p> <p>9 indicate the presence of other, as I think I</p> <p>10 mentioned before, other components that might be</p> <p>11 included in a bottle of talc.</p> <p>12 Q The only thing you were given was the Crowley</p> <p>13 report?</p> <p>14 A That is the only thing that I used that I have</p> <p>15 cited here. I relied on that, to use your</p> <p>16 terminology. There may be other things included</p> <p>17 that I reviewed.</p> <p>18 Q And then with respect to your opinions on the</p> <p>19 relevance of these fragrance chemicals, I would</p> <p>20 like to better understand if the opinion -- the</p> <p>21 summary that you have of the Crowley report from</p> <p>22 11 to 12, do you see that?</p> <p>23 A Yes, I do.</p> <p>24 Q Are you simply noting what you are reading from</p> <p>25 Crowley's report?</p>
<p style="text-align: right;">Page 143</p> <p>1 cause ovarian cancer?</p> <p>2 MS. PARFITT: Objection to form.</p> <p>3 A I did not do a systematic review looking for</p> <p>4 articles, nor am I aware of any.</p> <p>5 Q With regards to fragrances, you cite the Crowley</p> <p>6 report, correct?</p> <p>7 A Yes.</p> <p>8 Q Is the sole basis for the passage of your report</p> <p>9 talking about the presence of fragrances and</p> <p>10 powders, is the sole basis for that passage in</p> <p>11 Crowley's report?</p> <p>12 A I believe that is the main one that I cite.</p> <p>13 But without meaning to be flippant, anyone</p> <p>14 who has smelled Johnson & Johnson Baby Powder and</p> <p>15 Shower to Shower can smell the fragrance in those.</p> <p>16 It's no surprise to me.</p> <p>17 To say there were X number of fragrance</p> <p>18 chemicals, you know, 175 between those two</p> <p>19 products, yeah, that is the only source I have for</p> <p>20 those numbers.</p> <p>21 But the idea that these are highly scented</p> <p>22 products, anybody could tell that still has a</p> <p>23 sense of smell.</p> <p>24 Q Do you have any knowledge concerning the testing</p> <p>25 that is performed on talcum powders with regard to</p>	<p style="text-align: right;">Page 145</p> <p>1 Are you offering these opinions as your</p> <p>2 own?</p> <p>3 A I'm summarizing there what was in Crowley's</p> <p>4 report.</p> <p>5 Q In that last sentence you say, "He concluded that</p> <p>6 these chemicals contained inflammatory properties</p> <p>7 and were potentially carcinogenic."</p> <p>8 Do you see that?</p> <p>9 A Yes, I see that statement.</p> <p>10 Q There you are referring to Dr. Crowley's</p> <p>11 conclusions, correct?</p> <p>12 A Correct.</p> <p>13 Q Have you, as a scientist, independently reached</p> <p>14 those conclusions?</p> <p>15 A Again, I did not perform a systematic review of</p> <p>16 fragrances and whether or not they contained</p> <p>17 inflammatory properties and the carcinogenic</p> <p>18 potential.</p> <p>19 I do not conclude that. I clearly state that</p> <p>20 that is what he concluded and I cited that.</p> <p>21 Q In the sentences above when you are reporting</p> <p>22 classifications from the EPA and the IARC, you are</p> <p>23 reporting Dr. Crowley's reporting of those</p> <p>24 classifications?</p> <p>25 A Correct.</p>

Page 146	Page 148
1 MS. PARFITT: Objection to the form.	1 Do you see that?
2 Q You did not independently look at those	2 A Yes.
3 classifications, correct?	3 Q Did you write these sections?
4 A Correct. I did not go back to confirm that they	4 A I did. Well, before I say that, you see that I do
5 were in those categories. That is correct.	5 have big sections quoted in there. Those were
6 Q Do you know if Dr. Crowley considered dosage in	6 direct quotes that I pulled off the website.
7 his report?	7 Yes, the rest of this I wrote.
8 Did you look at that?	8 Q On Page 3 of your report you mention that the
9 MS. PARFITT: Objection. Form.	9 mandate that you had in this case was to comment
10 A Dosage of what?	10 on general cause, correct?
11 Q Let me ask a different question.	11 A Yes.
12 A Okay.	12 Q Do these two sections on the discontinuation and
13 Q Do you recall reading if he did any sort of risk	13 the "Facts About Talc" and Cancer-related
14 assessment?	14 Lawsuits, do those fit within your mandate?
15 Do you recall reading that in his report?	15 A Well, let's take them section by section.
16 A A risk assessment associated with fragrance and	16 Which one do you want to talk about first?
17 ovarian cancer?	17 Q Sure. Are you intending to offer expert opinions
18 Q Correct.	18 on the reason Johnson & Johnson discontinued
19 A I do not recall that in that report.	19 talcum powders?
20 Q Are you aware of any studies or data showing that	20 A No, I'm not going to offer an expert opinion on
21 any of these fragrance chemicals can cause cancer?	21 the reasons why Johnson & Johnson did. I don't
22 A No, I did not do a comprehensive review of that.	22 know what those reasons are.
23 I believe this report, similar to my report here,	23 But I am offering just kind of evidence that
24 was kind of also entered under oath. It was part	24 Johnson & Johnson did recall about 33,000 bottles
25 of a deposition or an expert report.	25 of baby powder in October of 2019 after the FDA
Page 147	Page 149
1 Q Understood. With respect to fragrances, to the	1 found asbestos in a bottle of it.
2 extent I've not asked this, did you ask to see if	2 Also, then the statement that was released by
3 any experts for the defense have commented on or	3 Johnson & Johnson on their Facts about Talc
4 addressed fragrance chemicals in their reports?	4 website.
5 A Again, I did not request anything from the	5 Q And are you intending to offer opinions on Johnson
6 defense.	6 & Johnson's state of mind or corporate
7 Q I asked this question earlier about asbestos.	7 motivations?
8 With respect to all of these other components	8 A No. I don't believe that I have any intention of
9 that you mention or allege in your report, fibrous	9 offering state of mind or anything. It's really
10 talc, heavy metals, fragrance chemicals, are those	10 just showing what the response was to the
11 constituents necessary to your causation opinion?	11 statement earlier about, you know, what I
12 MS. PARFITT: Objection to form.	12 mentioned earlier about the testing in
13 A No. My causation opinion, again, is that talcum	13 October 2018.
14 powder whatever the components are within the	14 Q Is it your opinion or your guess, or how would you
15 bottles, or bottles more accurately, that are used	15 characterize it as to why Johnson & Johnson
16 by a person across their lifespan. It is not any	16 discontinued talcum powders?
17 one particular component.	17 MS. PARFITT: Objection to form.
18 Q Let's move on to Page 12 and 13 of your report.	18 A When you say they discontinued talcum powders,
19 A Yes.	19 have they, I mean, they pulled them off their
20 Q You have included on this page two sections of	20 shelves in response to this.
21 your report.	21 I don't have any idea as to why they would
22 One is titled Johnson & Johnson	22 discontinue sales of talc-based powder. I don't
23 Discontinuation of Talc-based Johnson's Baby	23 study market share or any of that.
24 Powder. The other is titled "Facts about Talc"	24 Q Are you intending to offer expert opinions on
25 and Cancer-related Lawsuits.	25 whether Johnson & Johnson published truthful

<p style="text-align: right;">Page 150</p> <p>1 information on its website?</p> <p>2 MS. PARFITT: Objection to form.</p> <p>3 A I'm not rendering an opinion at all about whether</p> <p>4 it's truthful information or not.</p> <p>5 Q Are you intending to offer expert opinions on the</p> <p>6 psychology of consumers to be able to read and</p> <p>7 decipher information available on these websites?</p> <p>8 A What section are you referring to?</p> <p>9 Q I'm just asking you in general.</p> <p>10 Do you have opinions on the psychology of</p> <p>11 consumers to read information posted on these</p> <p>12 websites?</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 A Yeah. No. I have no opinion on the psychology of</p> <p>15 consumers, that was the first part.</p> <p>16 And the second part I think I state in this</p> <p>17 part Number 3, Facts About Talc, you know, when,</p> <p>18 again, I was kind of driven to the website looking</p> <p>19 after -- the FDA safety report was what got me to</p> <p>20 the Johnson & Johnson Facts About Talc.</p> <p>21 In an effort to do just a good review of the</p> <p>22 background of -- again, I'm new to this field.</p> <p>23 I'm certainly new to the litigation world, what</p> <p>24 was actually going on with it, that drove me to</p> <p>25 this website.</p>	<p style="text-align: right;">Page 152</p> <p>1 A I am not debating as to whether there have been</p> <p>2 thousands of tests. I don't have that data</p> <p>3 available.</p> <p>4 I am debating the statement that it says "Our</p> <p>5 talc has also been tested and confirmed to be</p> <p>6 asbestos free" simply because that directly</p> <p>7 contradicts the U.S. FDA report and that, you</p> <p>8 know, the company then pulled these from the</p> <p>9 shelf.</p> <p>10 Q Does Johnson & Johnson address the FDA testing on</p> <p>11 its website?</p> <p>12 A I do not know if they address that directly on the</p> <p>13 website. I am assuming that they do because, as</p> <p>14 you mention, they have -- or as I mentioned</p> <p>15 here -- over 3,200 documents. So I do think that</p> <p>16 that is among it.</p> <p>17 Q Do you dispute that Johnson & Johnson's talc comes</p> <p>18 from ore sources confirmed to meet stringent</p> <p>19 specifications.</p> <p>20 Do you dispute that?</p> <p>21 MS. PARFITT: Objection. Form.</p> <p>22 A I have no idea where these sources are, outside</p> <p>23 of, like I said, most currently I believe it's</p> <p>24 sourced in China.</p> <p>25 Q Do you dispute that talcum powders are routinely</p>
<p style="text-align: right;">Page 151</p> <p>1 And, you know, I was, indeed, very surprised</p> <p>2 to see under the Review of Evidence tab there was</p> <p>3 a link to a drop box that contained over 3,200</p> <p>4 different documents at that time.</p> <p>5 And I do offer the opinion that I think it's,</p> <p>6 that is a lot of documents to sort through for</p> <p>7 anybody, particularly somebody who does not have</p> <p>8 any training in either science or in the legal</p> <p>9 system.</p> <p>10 Q Do you understand that those documents are posted</p> <p>11 and available to the general public, media, other</p> <p>12 scientists?</p> <p>13 A Yes, I understand that.</p> <p>14 Q Are you claiming that there is information or</p> <p>15 documents that they should have posted but they</p> <p>16 didn't?</p> <p>17 MS. PARFITT: Objection to form.</p> <p>18 A No, I'm not claiming that at all.</p> <p>19 Q Your second block quote leads with "Thousands of</p> <p>20 tests."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q Are you disputing that there have been thousands</p> <p>24 of tests that confirm that the products do not</p> <p>25 contain asbestos?</p>	<p style="text-align: right;">Page 153</p> <p>1 tested?</p> <p>2 This is in the third sentence.</p> <p>3 MS. PARFITT: Objection. Asked and</p> <p>4 answered.</p> <p>5 A Where is this?</p> <p>6 Q This is a block quote that you included.</p> <p>7 It says, "Not only is our talc routinely</p> <p>8 tested..."</p> <p>9 Do you dispute that the talc is routinely</p> <p>10 tested?</p> <p>11 A I don't have knowledge of whether or not it is</p> <p>12 routinely tested.</p> <p>13 Q And, again, you just agreed with me that Johnson &</p> <p>14 Johnson does discuss the FDA 2019 testing on its</p> <p>15 website, correct?</p> <p>16 That is where you can find it, is that</p> <p>17 correct?</p> <p>18 A I believe that they have at least a press release</p> <p>19 related to that, yes.</p> <p>20 Q And they have a statement explaining it, is that</p> <p>21 correct?</p> <p>22 MS. PARFITT: Objection to form.</p> <p>23 Q And explaining Johnson & Johnson's position on it,</p> <p>24 correct?</p> <p>25 A I don't have that cited here or in front of me so</p>

<p style="text-align: right;">Page 154</p> <p>1 I can't say as to whether it's correct or not.</p> <p>2 Q And when Johnson & Johnson refers to testing that</p> <p>3 has confirmed the talc to be asbestos free by a</p> <p>4 range of independent laboratories and</p> <p>5 universities, do you have any reason to dispute</p> <p>6 that?</p> <p>7 MS. PARFITT: Objection. Form.</p> <p>8 A I did not look for any of this information amongst</p> <p>9 the 3,200 documents that were in the drop box</p> <p>10 provided by Johnson & Johnson.</p> <p>11 Q In the first paragraph in the "Facts About Talc"</p> <p>12 section you include the sentence that the website,</p> <p>13 the statement on the website "only includes a</p> <p>14 handful of studies, and none of them are directly</p> <p>15 referenced."</p> <p>16 Do you see that?</p> <p>17 A Right.</p> <p>18 Q What does that mean when you say "none of them are</p> <p>19 directly referenced"?</p> <p>20 Did you see on the website there are multiple</p> <p>21 studies actually cited and referenced?</p> <p>22 A They are cited and referenced, but they don't</p> <p>23 necessarily point to different areas where, like,</p> <p>24 that exact citation matched to something that was</p> <p>25 printed on the website.</p>	<p style="text-align: right;">Page 156</p> <p>1 referenced.</p> <p>2 Q Okay.</p> <p>3 A You know, so looking at it, I would, you know,</p> <p>4 like, I can't look at it and say, okay, number --</p> <p>5 I mean, I can because this was the literature I</p> <p>6 reviewed -- but someone in the public could not</p> <p>7 look at it and say, okay, Gonzales, that is</p> <p>8 associated with the Sister Study.</p> <p>9 That is what I meant by direct reference,</p> <p>10 that I didn't see the footnote in the body of the</p> <p>11 web page here.</p> <p>12 Q Okay. Then you finish this section with a comment</p> <p>13 that you say, beginning at the end of Page 12 you</p> <p>14 said, "Finally, under the 'News' tab, there are</p> <p>15 many statements in response to the various ongoing</p> <p>16 litigations for both mesothelioma and ovarian</p> <p>17 cancer, which give the illusion of full</p> <p>18 transparency."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q Is that an expert opinion that you intend to offer</p> <p>22 to the jury?</p> <p>23 MS. PARFITT: Objection to form.</p> <p>24 A My expert opinion is really based on the science.</p> <p>25 It's not necessarily based on any of this</p>
<p style="text-align: right;">Page 155</p> <p>1 The link provided at that time was broken,</p> <p>2 the one that linked to the American Cancer</p> <p>3 Society. That may be fixed now. When I was</p> <p>4 looking at this a couple days before this report</p> <p>5 was due, it was unavailable. It was down.</p> <p>6 Q I printed off a copy of the study's tab on the</p> <p>7 "Facts About Talc" website.</p> <p>8 A Okay.</p> <p>9 Q I guess I will mark this as Exhibit 11.</p> <p>10 (EXHIBIT NUMBER 11 WAS MARKED FOR</p> <p>11 IDENTIFICATION.)</p> <p>12 Q I'm just trying to clarify the statement in the</p> <p>13 report when you say "none of them are directly</p> <p>14 referenced."</p> <p>15 That is the terminology that you used,</p> <p>16 correct?</p> <p>17 A I believe so, yes.</p> <p>18 Q Okay. And if we look at the last page of the</p> <p>19 statement whether or not you agree with the</p> <p>20 statement, there is a list of references. It</p> <p>21 directly identifies studies, correct?</p> <p>22 A It directly identifies studies. I'm missing where</p> <p>23 the footnotes are in here. So I would expect to</p> <p>24 see, you know, something, like, with a little</p> <p>25 footnote in one. That is what I mean by directly</p>	<p style="text-align: right;">Page 157</p> <p>1 supporting documentation.</p> <p>2 Q For that sentence, are there any particular news</p> <p>3 statements that you are referring to?</p> <p>4 A No. It's kind of as a whole. There is all of</p> <p>5 this literature -- or not even literature --</p> <p>6 there's all of these statements and different</p> <p>7 things that I think when you look at it you think,</p> <p>8 wow, everything is here.</p> <p>9 In my review, it's almost impossible to go</p> <p>10 through it in any sort of systematic way just</p> <p>11 based on how it's arranged and just the sheer</p> <p>12 magnitude of the information there.</p> <p>13 Q There have been a lot of documents in this</p> <p>14 litigation.</p> <p>15 You understand that?</p> <p>16 A Absolutely, yes.</p> <p>17 Q And you understand that, again, those documents</p> <p>18 are posted to be available to those who might be</p> <p>19 interested in seeing them, correct?</p> <p>20 A Correct.</p> <p>21 MS. PARFITT: Objection. Asked and</p> <p>22 answered.</p> <p>23 Q Are you claiming that Johnson & Johnson has</p> <p>24 violated some sort of industry standard or other</p> <p>25 standard for posting these materials?</p>

<p style="text-align: right;">Page 158</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 A That was not my charge, nor my intent.</p> <p>3 Q You are aware that there are scientists, both</p> <p>4 internally and externally, who disagree with the</p> <p>5 claims being made in this litigation, is that</p> <p>6 correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 A I think there are probably scientists internally</p> <p>9 and externally that agree with claims on both</p> <p>10 sides being made. That is part of why we are</p> <p>11 here.</p> <p>12 Q Do you agree that Johnson & Johnson has the right</p> <p>13 to make public its views on the scientific</p> <p>14 evidence and the merit of this talc litigation?</p> <p>15 MS. PARFITT: Objection to form.</p> <p>16 A I believe that Johnson & Johnson has the right to</p> <p>17 put forward whatever documentation they want to</p> <p>18 for whatever purposes they want to.</p> <p>19 Q And do you believe that external scientists who</p> <p>20 disagree with these claims being made in this</p> <p>21 litigation have a right to have a voice in a</p> <p>22 public forum?</p> <p>23 MS. PARFITT: Objection to form.</p> <p>24 A Yes. So when you say "these claims" what do you</p> <p>25 mean?</p>	<p style="text-align: right;">Page 160</p> <p>1 MS. PARFITT: Good place to stop?</p> <p>2 MR. JAMES: Yes.</p> <p>3 (OFF RECORD AT 12:32 P.M.)</p> <p>4 (AT THIS TIME A SHORT RECESS WAS HELD OFF</p> <p>5 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS</p> <p>6 WERE HAD:)</p> <p>7 (ON RECORD AT 1:25 P.M.)</p> <p>8 BY MR. JAMES:</p> <p>9 Q Good afternoon, Dr. Cote.</p> <p>10 A Hello.</p> <p>11 Q With respect to the methodology that you followed</p> <p>12 in this case, have you applied the same</p> <p>13 methodology that you would in your professional</p> <p>14 career?</p> <p>15 A Yes. With respect to the methodology of how I put</p> <p>16 the report together, how I analyzed the studies, I</p> <p>17 started with, you know, a pull from some publicly</p> <p>18 available database of peer reviewed literature.</p> <p>19 I went through the literature. I went</p> <p>20 through the reference section for additional</p> <p>21 sources. I started my comprehensive review kind</p> <p>22 of going through the literature study by study.</p> <p>23 I tried to pull out similar elements like</p> <p>24 sample size and different characteristics about</p> <p>25 each individual study. And that was my</p>
<p style="text-align: right;">Page 159</p> <p>1 Q Sure. I will be more precise.</p> <p>2 You acknowledge that there are scientists who</p> <p>3 do not think talcum powders cause ovarian cancer,</p> <p>4 correct?</p> <p>5 A Yes, I believe that.</p> <p>6 Q And those scientists can exist both internally</p> <p>7 with Johnson & Johnson and externally, is that</p> <p>8 correct?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 A Correct. I believe there are scientists both</p> <p>11 internally and externally that may disagree.</p> <p>12 Q And although you may not agree with the position</p> <p>13 of Johnson & Johnson as reflected in some of these</p> <p>14 statements --</p> <p>15 A Correct.</p> <p>16 Q -- do you believe that the scientists have a right</p> <p>17 to express their views on the science?</p> <p>18 A Yes, I believe scientists have the right to</p> <p>19 express views on the science.</p> <p>20 Q Wrapping this up, do you intend to offer any</p> <p>21 expert opinions on the topics of business</p> <p>22 practices or corporate conduct?</p> <p>23 A I do not plan on offering any expert opinions on</p> <p>24 those two areas, business practices or corporate</p> <p>25 conduct.</p>	<p style="text-align: right;">Page 161</p> <p>1 methodology for the association part of the</p> <p>2 epidemiologic research.</p> <p>3 For the causal part of it, that is, you know,</p> <p>4 reliant on various different areas, you know, from</p> <p>5 anything from looking at biologic plausibility as</p> <p>6 we talked about this morning, trying to look at</p> <p>7 different lines of evidence there. Trying to look</p> <p>8 at things like specificity.</p> <p>9 There are two different reviews. One is more</p> <p>10 focused on my area of direct expertise looking at</p> <p>11 the association studies and the epidemiologic</p> <p>12 literature.</p> <p>13 And then the second piece of that was the</p> <p>14 causal. That is what we teach. That is what I do</p> <p>15 before I start, say, writing a grant. That all</p> <p>16 goes into kind of the rigor of developing a</p> <p>17 research question and the methodology to answer</p> <p>18 the question.</p> <p>19 Q Do you agree that in your professional capacity as</p> <p>20 an epidemiologist that you do not rely on</p> <p>21 unpublished litigation reports from paid experts?</p> <p>22 MS. PARFITT: Objection to form.</p> <p>23 A Yes. As an epidemiologist when I'm writing papers</p> <p>24 and things I do not rely on unpublished litigation</p> <p>25 reports.</p>

<p style="text-align: right;">Page 162</p> <p>1 Q Yes or no, do you agree in the field of 2 epidemiology that there is a generally accepted 3 hierarchy of epidemiologic study design?</p> <p>4 A No.</p> <p>5 Q Have you ever seen a hierarchy design illustration 6 in an epidemiologic textbook?</p> <p>7 A Yes, I'm aware of what you are referring to.</p> <p>8 Q Have you ever handed one out to your students in 9 class?</p> <p>10 MS. PARFITT: Objection to form.</p> <p>11 A I do not believe we have ever handed one out, no.</p> <p>12 Q Have you --</p> <p>13 A I co-teach.</p> <p>14 Q Have you ever taught that prospective cohort 15 studies, in general, are viewed to have a superior 16 design as compared to retrospective case control 17 studies?</p> <p>18 A I have definitely heard that before. I have seen 19 it in some textbooks.</p> <p>20 But, no, I do not believe I have taught, nor 21 do I believe that one is superior to the other.</p> <p>22 Both of them -- how we have always taught it is 23 almost, we separate them out into case control and 24 cohort into two columns. And we talk about the 25 strengths of each one.</p>	<p style="text-align: right;">Page 164</p> <p>1 Q Do you believe that randomized controls are 2 superior to cohort and case control studies?</p> <p>3 Just yes or no.</p> <p>4 A I can't answer that yes or no. It depends on the 5 research question. Randomized control trials are 6 outside of the scope of epidemiology.</p> <p>7 Epidemiology is an observational science. We do 8 not assign different people to groups.</p> <p>9 That study design is not even really 10 considered as an epidemiologic type of study.</p> <p>11 Q Have you ever published an epidemiologic case 12 control study on a topic of interest and in that 13 study cited the need for further research on 14 that same topic, but with prospective cohort 15 data?</p> <p>16 A You know, I have somewhere around 140 different 17 publications. I can't say I have ever said we 18 need prospective data.</p> <p>19 I think there are certain cases where we 20 could. In almost all of our studies we do say we 21 need additional research in that area.</p> <p>22 Q I will mark as Exhibit 12 a 2016 paper in the 23 British Journal of Cancer on Analgesic Medication 24 Use and Risk Of Epithelial Ovarian Cancer In 25 African-American Women.</p>
<p style="text-align: right;">Page 163</p> <p>1 So, like, for a cohort study, the strength of 2 the study is, well, first, how you would select 3 your study population is based on an exposure. 4 That exposure can be something like in the Women's 5 Health Initiative, it was being a post-menopausal 6 woman.</p> <p>7 Or it could be based on some sort of known 8 occupational exposure. And then you can study 9 many outcomes. That is the strength of the cohort 10 study, is many outcomes.</p> <p>11 Case control, what that is, is you can study 12 one outcome because you select your population 13 based on whether or not they have the disease of 14 interest.</p> <p>15 And then you can study many different 16 exposures and that is the strength of that. They 17 tend to be -- case control studies are better for 18 rare diseases. Cohort studies are better for more 19 common diseases.</p> <p>20 That is how we teach them versus a hierarchy 21 of this is the best and this is the worst. Both 22 of those, case control and cohort, are both 23 hypothesis testing study designs versus something 24 like a cross-sectional study, which is just 25 hypotheses generating.</p>	<p style="text-align: right;">Page 165</p> <p>1 (EXHIBIT NUMBER 12 WAS MARKED FOR 2 IDENTIFICATION.)</p> <p>3 A Okay.</p> <p>4 MS. PARFITT: That is 2016.</p> <p>5 MR. JAMES: That is 2016.</p> <p>6 MS. PARFITT: Exhibit 12?</p> <p>7 MR. JAMES: Yes.</p> <p>8 Q So here you are studying analgesics and risk of 9 ovarian cancer, correct?</p> <p>10 A Yes.</p> <p>11 Q Flip it to Page 824. Just to be clear, you are an 12 author on this paper?</p> <p>13 A Yes.</p> <p>14 Q You see here that on Page 824 that in the top and 15 last paragraph it says, "In conclusion, this study 16 supports previous evidence that any NSAID use, but 17 not acetaminophen, is inversely associated with 18 EOC risk."</p> <p>19 Do you see that?</p> <p>20 A I do, yes.</p> <p>21 Q And then the last sentence says -- of that same 22 paragraph -- "Future research, specifically in 23 large cohort studies, is needed in order to fully 24 elucidate the impact of analgesic drug use on EOC 25 risk in African-American women, as well as other</p>

<p style="text-align: right;">Page 166</p> <p>1 underrepresented racial groups."</p> <p>2 Do you see that?</p> <p>3 A I do.</p> <p>4 Q Is the reference to the cohort studies in that sentence, is that referencing prospective cohort data?</p> <p>7 A I would believe so, yes.</p> <p>8 Q Again, this paper specifically pertains to a risk factor for ovarian cancer, correct?</p> <p>10 A Correct.</p> <p>11 Q The language of the paper of which you are a co-author is that the cohort data is, quote, needed in order to fully elucidate the impact.</p> <p>14 Do you see that?</p> <p>15 A Yes. The final sentence.</p> <p>16 Q And the one that I just read, again, the terminology there that you use, or the authors including you, have used "is needed," correct?</p> <p>19 A Correct.</p> <p>20 Q Here in this paper you are at least acknowledging the need for prospective cohort data on an ovarian cancer risk factor, correct?</p> <p>23 A Yes.</p> <p>24 Q And you want that data so you can fully elucidate the impact of that risk factor, correct?</p>	<p style="text-align: right;">Page 168</p> <p>1 correct?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 A Correct.</p> <p>4 Q You do agree that case control studies may be more prone to recall bias, correct?</p> <p>6 MS. PARFITT: Objection. Form.</p> <p>7 A More prone compared to what?</p> <p>8 Q Look at your report on Page 8.</p> <p>9 A Yes.</p> <p>10 Q Near the bottom of Page 8 you have a definition for recall bias, correct?</p> <p>12 A Yes.</p> <p>13 Q And in the third line down you say, "Case control studies may be more prone to this type of bias."</p> <p>15 Do you see that?</p> <p>16 A Yes.</p> <p>17 Q So here you are referring to recall bias, is that correct?</p> <p>19 A That is correct.</p> <p>20 Q So, again, you would acknowledge that case control studies may be more prone to recall bias, is that correct?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 A I would note that in addition to the statement that the key difference is whether recall varies</p>
<p style="text-align: right;">Page 167</p> <p>1 A Correct.</p> <p>2 Q This paper was authored before you were retained as an expert in this litigation, correct?</p> <p>4 A Correct.</p> <p>5 Q Has your opinion on the value of prospective cohort data to evaluate ovarian cancer risk factor changed since you wrote this paper?</p> <p>8 A No, I believe that there is value to both case control and cohort studies with respect to looking at risk factors for ovarian and other cancers.</p> <p>11 Q But here you noted that cohort data was needed to fully elucidate the impact of the risk factor, correct?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 A That is the statement as written. I don't necessarily have to a hundred percent agree with the word "fully."</p> <p>18 Q The language used in that sentence imports that cohort data, right, is needed, correct?</p> <p>20 MS. PARFITT: Objection. Asked and answered.</p> <p>22 A Cohort data is needed.</p> <p>23 Q So you had case control data. But now you want, as an author, you want cohort data to fully elucidate what is going on with analgesics,</p>	<p style="text-align: right;">Page 169</p> <p>1 by the outcome of interest.</p> <p>2 And so there are certain -- and about what the exposure is. There are certain exposures that may be more prone to recall bias than other exposures.</p> <p>6 Q Sure. But just, again, quoting the language of your report, it is not my language, you do have in your report, "Case control studies may be more prone to this type of bias."</p> <p>10 There you are referring to recall bias in that sentence, correct?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 A Correct.</p> <p>14 Q As you know, at the bottom it says, "The key difference is that recall varies by the outcome of interest," correct?</p> <p>17 A Yes.</p> <p>18 Q And so there are some things that are more prone to recall bias than others, correct?</p> <p>20 A Some exposures.</p> <p>21 Q Fair enough. A more scientific term.</p> <p>22 A Yes.</p> <p>23 Q There are some exposures that are studied in epidemiology that are more prone to recall bias, is that correct?</p> <p>25</p>

<p style="text-align: right;">Page 170</p> <p>1 A Yes.</p> <p>2 Q And certainly that would be exposures that, for 3 example, are not verifiable by medical records, 4 correct?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 A I don't know if you could say that. I mean, the 7 reason that you would use medical records would be 8 to confirm something.</p> <p>9 I don't know if those factors that you 10 confirm on medical records would be more or less 11 prone to recall bias.</p> <p>12 You would be talking about a way to help 13 address or reduce recall bias, but it does not 14 necessarily mean that factors that are available 15 through medical record review are more or less 16 prone to recall bias.</p> <p>17 You would just have an additional way to 18 verify them.</p> <p>19 Q You are aware that in the literature, whether or 20 not you agree with it or not, but in the 21 literature, many authors have noted that talc 22 usage is one of the outcomes that is especially 23 prone to recall bias, correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 A I would be interested in seeing that literature.</p>	<p style="text-align: right;">Page 172</p> <p>1 A So when you are asking me to judge is ever never 2 best or not, there is always, when we are writing 3 the questionnaires for the women there is usually 4 a timeframe given. We need to look at the 5 timeframe.</p> <p>6 Q Do you believe for purposes of recall bias, I 7 think this is what you just said, but for purposes 8 of recall bias in the talc studies, ever never 9 measurement is subject to less recall bias than 10 measurements by frequency or duration or 11 cumulative life exposures?</p> <p>12 A Again, based on timing and some other factors, 13 ever never may be less likely to have recall bias 14 introduced.</p> <p>15 Some of that is just based on the timing of 16 when the question is being asked of the women and 17 based on kind of the window or the timeframe you 18 are asking the question.</p> <p>19 So it's hard to just give a one yes or no 20 answer there.</p> <p>21 Q On Page 10 and Page 11 of your report you have a 22 section on the Risk Factors. Flip to that for me.</p> <p>23 A Okay.</p> <p>24 Q In there you set forth a paragraph or a discussion 25 of modifiable risk factors for ovarian cancer and</p>
<p style="text-align: right;">Page 171</p> <p>1 One of the things that I had read, I want to say 2 it was one of O'Brien's papers, was that 3 especially for ever never exposure they felt like 4 that was an exposure that was not particularly 5 prone to recall bias.</p> <p>6 Q Do you believe ever never is the best way to 7 measure talc usage?</p> <p>8 A Unfortunately, I don't think we have a gold 9 standard yet of talc usage. I think that ever 10 never is also not complete when we don't talk 11 about things like timeframe.</p> <p>12 There were certain studies, for instance, the 13 Sister Study was a cohort study. And I think it 14 was a very good example of where the exposure was 15 only collected initially, when initially asked it 16 was only collected for the very recent history. 17 And it was an extraordinary low proportion of 18 women who reported using talc.</p> <p>19 And then when they went back and said, okay, 20 how about between the ages of ten and thirteen, we 21 saw then almost a doubling of the women who had 22 used it.</p> <p>23 So ever never still -- there's more 24 information needed than ever never.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">Page 173</p> <p>1 non-modifiable risk facts, correct?</p> <p>2 A Correct.</p> <p>3 Q Do those listings represent your professional 4 judgment on the current list of risk factors for 5 ovarian cancer?</p> <p>6 A Yeah. I mean, I pulled this from a couple 7 different reviews, like an umbrella review and 8 another systematic review of risk factors. I was 9 comfortable with this list that I provided.</p> <p>10 Q Risk factor can mean different things, correct?</p> <p>11 A Sure. Sure.</p> <p>12 Q For these that you have listed, do you believe 13 that all of these risk factors that you have 14 listed on Pages 10 and 11 have been shown to be 15 causally associated with either a protective 16 effect or an increased risk for ovarian cancer?</p> <p>17 A No. I was not assessing causality at all with 18 these.</p> <p>19 These are things that have been associated in 20 epidemiologic studies.</p> <p>21 Q Understood. For genetics do you realize there is 22 literature demonstrating additional genetic 23 variance and mutations that are considered risk 24 factors for ovarian cancer other than BRCA1 and 25 BRCA2?</p>

<p style="text-align: right;">Page 174</p> <p>1 A Yes. I list one right here. Lynch syndrome or 2 NNPCC, that is one. There are other rare familial 3 syndromes that also increase risk of ovarian 4 cancer and other cancers.</p> <p>5 Q Are you familiar with the emerging literature on 6 the FANC mutation as a risk factor for ovarian 7 cancer?</p> <p>8 A I don't know if I'm, if I would classify myself as 9 familiar with that, no. I did not do a review of 10 the genetics of ovarian cancer.</p> <p>11 Q Have you seen a paper or papers where FANC is now 12 being discussed as a genetic risk or a potential 13 risk factor for ovarian cancer?</p> <p>14 A I cannot pull one from my brain with an author or 15 even a date right now. I would be happy if you 16 have one available that I would review it and give 17 you my thoughts.</p> <p>18 Q In this list of risk factors that you have here, 19 just to confirm again in this list, you have not 20 listed asbestos fibrous talc, heavy metals, or 21 fragrances as standalone risk facts, is that 22 correct?</p> <p>23 MS. PARFITT: Objection.</p> <p>24 A As standalone risk factors, no. But general use 25 of talcum powder is, yes.</p>	<p style="text-align: right;">Page 176</p> <p>1 kind of takes away the majority of the tissue that 2 is at risk. Leaving the fallopian tubes you may 3 still may be at risk. Even removal of both 4 sometimes, you know, there is tissue remaining. 5 But is there a hormonal component in there? 6 Yes.</p> <p>7 Q Have you seen literature talking about how, for 8 example, the removal of tubes can lessen the risk 9 because the fimbriae ends of the tubes are no 10 longer present?</p> <p>11 A That it is a disruption, yes.</p> <p>12 Q And that is where cancer is thought to -- some 13 people have posited that that is where high grade 14 serous cancer is thought to originate from, 15 correct?</p> <p>16 A Right. Certain subtypes of EOC may originate in 17 the fallopian tubes, yes.</p> <p>18 Q Have you published on other -- you have published 19 on other potential risk factors for ovarian 20 cancer, correct?</p> <p>21 A Yes. Probably at least twenty different ones if I 22 had to ballpark a number.</p> <p>23 Q Okay. I have glanced at a few of them. I will 24 tick them off and ask if those sound familiar.</p> <p>25 A Okay.</p>
<p style="text-align: right;">Page 175</p> <p>1 Q We have talked about those topics in sufficient 2 detail this morning, correct?</p> <p>3 A Yes, we did.</p> <p>4 Q With respect to your commentary on hysterectomy 5 and oophorectomy -- do you see that?</p> <p>6 A Yes.</p> <p>7 Q Do you recognize that one explanation for 8 reduction in risk associated with hysterectomy, 9 oophorectomy has been a less than hormonal risk as 10 a result of those procedures?</p> <p>11 A Meaning? Can you rephrase?</p> <p>12 Q That was a terrible question. Let me start over. 13 So you have commented here about protective 14 effects from various procedures, correct?</p> <p>15 A Yes.</p> <p>16 Q You understand in the literature that there have 17 been various hypotheses posited as to why that may 18 be so, correct?</p> <p>19 A Correct.</p> <p>20 Q Have you seen some literature talking about how 21 those procedures lessen the hormonal impact on 22 ovaries or the surrounding tissues?</p> <p>23 A Well, an oophorectomy is a removal of the ovaries. 24 Yes, that would -- for many things. It reduces 25 your hormone levels systemically. Then it also</p>	<p style="text-align: right;">Page 177</p> <p>1 Q I have seen some literature where you looked at 2 overall healthy dietary pattern, high intake of 3 total sugars, cigarette smoking among 4 African-Americans, obesity and excessive adult 5 weight gain, pro-inflammatory diets, high calcium 6 low lactose diets, and family history of 7 pancreatic cancer.</p> <p>8 Are all of those topics that you recall 9 having published on over the course of your 10 career?</p> <p>11 A Yes. I think all of them except for the one at 12 the very end were part of the AACR study in 13 African-American women.</p> <p>14 The one at the end was very early on in my 15 career. It was a case control study of pancreatic 16 cancer. At the time it was -- it's more standard 17 now, but at the time I think they were exploring 18 other cancers that are associated with BRCA1 and 19 BRCA2 and other familial syndromes.</p> <p>20 We were able to show that in the pancreatic 21 families they had higher risk for ovarian cancer, 22 too.</p> <p>23 Q Are any of the factors that I just mentioned 24 factors that you recognize or consider to be 25 causal?</p>

<p style="text-align: right;">Page 178</p> <p>1 A I've not done that sort of review. So I -- can 2 you repeat the list? We can go one by one. 3 Q Sure. Let me ask you about specific ones. 4 Do you consider cigarette smoking among 5 African-Americans to be causally associated with 6 serous ovarian cancer, which is what I saw in your 7 paper? 8 A Causally associated? I've not done that analysis 9 recently so I would say no, I'm not aware that 10 there is a causal association. I would not make 11 that statement. 12 Q Do you consider obesity to be causally associated 13 with ovarian cancer? 14 A Again, I have not reviewed it comprehensively so I 15 would not make that statement. 16 Q When you have authored papers on other risk 17 factors for ovarian cancer or potential risk 18 factors, have you always adjusted for talc as a 19 confounder? 20 A How we kind of create our statistical models, 21 there are kind of two different ways. They are 22 complementary and we usually use them together. 23 The first is you come up with a number of 24 risk factors that apriori you know are probably 25 going to differ between your cases and controls.</p>	<p style="text-align: right;">Page 180</p> <p>1 Q With respect to migration, your opinions on 2 migration, we will shift to that. Okay? 3 A Sure. 4 Q Have you cited any studies that mimic what is 5 being alleged here, which is that talc applied 6 perineally can migrate up the female genital 7 tract? 8 A Let's look at that section where I discuss this. 9 Q I will go through some of those studies in a 10 moment. 11 A Yeah. 12 Q My question is, let me rephrase it. 13 Have you seen any studies that demonstrate 14 that following perineal talc application that talc 15 is migrating up the female genital tract? 16 MS. PARFITT: I will object to form. 17 A I've not seen those studies other than the one we 18 quoted in here that was about the use of talcum 19 powder or talc on gloves, like examination gloves. 20 But as for, you know, trying to get a group 21 of women to apply talc and then looking to see at 22 one hour, twelve hours, twenty-four hours if it 23 has migrated up into the reproductive system, no, 24 I've not seen that type of study published. 25 I think that would be very hard to get</p>
<p style="text-align: right;">Page 179</p> <p>1 So when you adjust the models you are not 2 putting in things that you know or believe to be 3 risk factors. They can be things like in the 4 AACEs study we adjust it by the site. By site I 5 mean geographic location was always included in 6 there just in case there were differences between 7 the cases and controls that were unaccounted for. 8 The second way is to look at univariate 9 analyses. That is looking at one exposure and 10 your outcome of interest one at a time. You set a 11 threshold based on, you know, sometimes it is not 12 even the regular P value of 0.5 for statistical 13 significance. Sometimes it is higher than that 14 because these are exploratory analyses. You can 15 make the decision to include those factors into 16 your model. 17 So it's usually some combination of apriori 18 and things that differ between your cases and 19 controls. They are not necessarily known risk 20 factors. 21 So as to have I always put talc in, getting 22 back to that piece of the question, I can't say we 23 have always put talc in. I did not review twenty 24 odd at least papers in that area to see if talc 25 was always included.</p>	<p style="text-align: right;">Page 181</p> <p>1 approved by a review board. 2 Q The studies that you do cite on Page 13 of your 3 report for migration, in the first paragraph you 4 cite a study that deals with carbon, you cite a 5 study that deals with ink, and you cite a study 6 that deals with radioactive tracers. 7 Those are the three that you cite in the 8 first paragraph, correct? 9 A Yes. 10 Q And do those studies mimic what is being alleged 11 here? 12 MS. PARFITT: Objection to form. 13 Q That perineal talc migrates up the genital tract. 14 Do they mimic? 15 Would you agree with that characterization or 16 not? Yes or no? 17 A No. The goal was not to mimic. It was to set the 18 stage and build the support for the idea, you 19 know, in the first one, which was in 1957, that 20 describes the cooperation of the musculature of 21 the female genital tract as a way to move sperm, 22 you know, up into, you know, into the vagina and 23 into where it can be ultimately fertilized. 24 So it's really trying to show a history of 25 what we knew about kind of normal female</p>

<p style="text-align: right;">Page 182</p> <p>1 functioning at the time.</p> <p>2 Q The Egli and Newton paper in particular, that</p> <p>3 study involved the deposition of carbon particles</p> <p>4 at the top of the vagina, correct?</p> <p>5 A Yes.</p> <p>6 Q The studies in the first paragraph that you cited</p> <p>7 are all significantly dissimilar as to what is</p> <p>8 being alleged here, correct?</p> <p>9 MS. PARFITT: Objection. Form.</p> <p>10 A How are they dissimilar?</p> <p>11 Q Let's mark the Egli paper as Exhibit 13.</p> <p>12 (EXHIBIT NUMBER 13 WAS MARKED FOR</p> <p>13 IDENTIFICATION.)</p> <p>14 Q On the second page, Page 152, under the method</p> <p>15 section do you see that second paragraph where it</p> <p>16 says "Three women"?</p> <p>17 A Yes.</p> <p>18 Q So they note that there was general anesthesia.</p> <p>19 The patient was placed in the -- how do you</p> <p>20 pronounce that -- lithotomy position?</p> <p>21 A Sounds good.</p> <p>22 Q "With her head tilted downward. The speculum was</p> <p>23 introduced into the vagina, and three to four</p> <p>24 millimeters of sterile carbon particles-Dextran</p> <p>25 suspension were deposited in the posterior fornix.</p>	<p style="text-align: right;">Page 184</p> <p>1 answered.</p> <p>2 A No. I believe that this study, is, as I stated</p> <p>3 previously, it's adding support to the idea that</p> <p>4 particles of various types can move from one area</p> <p>5 of the human female reproductive tract into</p> <p>6 another area of the reproductive tract.</p> <p>7 Did they test talc? No. Here they used</p> <p>8 carbon particles. I realize those are two</p> <p>9 different compounds.</p> <p>10 Q And under highly different conditions, correct?</p> <p>11 Here we have the use of oxytocin and that is</p> <p>12 very different than what is being alleged here,</p> <p>13 correct?</p> <p>14 MS. PARFITT: Objection. Form.</p> <p>15 A I don't know what you are alleging here.</p> <p>16 Oxycontin, from my understanding, makes muscle</p> <p>17 contractions. That's my understanding. That is</p> <p>18 something that they use to induce labor.</p> <p>19 There are other things that cause muscle</p> <p>20 contractions of the uterus like uterine cramps</p> <p>21 when a woman has her period.</p> <p>22 There are more similarities here that I think</p> <p>23 this question, this question alludes to.</p> <p>24 Q Do you agree or disagree that the study cited in</p> <p>25 this first paragraph of the biological mechanism</p>
<p style="text-align: right;">Page 183</p> <p>1 At the same time one milliliter of oxytocin was</p> <p>2 given intramuscularly."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Is that in any way similar to what is being</p> <p>6 alleged here that perineal, that a woman who</p> <p>7 applies talcum powders to her perineum, is it in</p> <p>8 any way similar to the hypothesis that as a result</p> <p>9 of applying talc to the perineum, that talc can</p> <p>10 migrate up the genital tract?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 A What this paper, and why this paper was cited, was</p> <p>13 to build support and a line of evidence suggesting</p> <p>14 that the tract was open.</p> <p>15 That things could be transmitted from one</p> <p>16 area of the female genital tract to other distant</p> <p>17 areas of the female genital tract.</p> <p>18 It's interesting that I think much of this</p> <p>19 work was around infertility. What they are</p> <p>20 showing here is that, yes, you can get foreign</p> <p>21 objects in here, it's carbon, from one area to</p> <p>22 another area.</p> <p>23 Q Yes or no, do you agree with me that this study is</p> <p>24 dissimilar to what is being alleged here?</p> <p>25 MS. PARFITT: Objection. Form. Asked and</p>	<p style="text-align: right;">Page 185</p> <p>1 section of your paper -- I will rephrase it.</p> <p>2 Do you believe that the studies in the first</p> <p>3 paragraph cited in that section are comparable to</p> <p>4 the allegation that perineal talc migrates up the</p> <p>5 female genital tract?</p> <p>6 Are they comparable?</p> <p>7 MS. PARFITT: Objection. Asked and</p> <p>8 answered.</p> <p>9 A Yes, I agree they are comparable based on the idea</p> <p>10 that there are, I should say lines of evidence</p> <p>11 that we, I, am trying to use in this report, which</p> <p>12 is different substances can move up the female</p> <p>13 genital tract.</p> <p>14 I believe that that supports the idea that</p> <p>15 talc could move up the female genital tract.</p> <p>16 Q Do you believe that the "idea" is the word that</p> <p>17 you use, is that an idea that has been</p> <p>18 scientifically proven?</p> <p>19 Is it still a theory? Or it is a hypothesis?</p> <p>20 A I believe that that hypothesis was addressed in</p> <p>21 this first paragraph on Page 13 talking about how</p> <p>22 sperm can move distally, how the carbon particles</p> <p>23 can move here into the fallopian tubes, and then</p> <p>24 the article from 1972 using another suspension of</p> <p>25 carbon.</p>

<p style="text-align: right;">Page 186</p> <p>1 Q Do you believe the claim that talc applied 2 perineally can migrate up the female genital tract 3 to the ovaries?</p> <p>4 Do you believe that claim is scientifically 5 proven, is still a theory, or is a hypothesis?</p> <p>6 A I believe based on -- let's go down to the third 7 paragraph here.</p> <p>8 "Human studies provide evidence in that talc 9 particles have been identified in ovarian tissue 10 in women with and without ovarian cancer."</p> <p>11 I believe -- so there was a 1971 report from 12 Henderson all of the way down to -- I'm trying to 13 look at the more frequent ones from February of 14 2020 that show that talc can migrate. I feel at 15 this point to me that is proof.</p> <p>16 Q With respect to your discussion of animal studies 17 you say on Page 13 "Animal studies do not provide 18 consistent evidence of translocation of talc - it 19 may be species-dependent."</p> <p>20 A Yes.</p> <p>21 Q Bottom line, animal studies, do you believe animal 22 studies demonstrate migration or translocation of 23 talc?</p> <p>24 A I believe that in certain species they do and in 25 certain species they do not. It is species</p>	<p style="text-align: right;">Page 188</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 A I'm happy to examine each of these. I don't 3 remember details in their method section or, you 4 know, discussions about limitations regarding, 5 like, the handling of these specimens after they 6 have been removed, kind of the processing piece of 7 it.</p> <p>8 Q Do you have expertise in the tissue processing 9 portion of this?</p> <p>10 A I have experience with it. I don't know if I 11 would say I have expertise. But most of my 12 research work has been in paraffin-embedded 13 tissue.</p> <p>14 Certainly right now I oversee a large tissue 15 bank of fresh frozen and formalin fixed tissue. 16 I'm very familiar with standard operating 17 procedures that are used in handling specimens 18 like this.</p> <p>19 Q So you are aware there are multiple steps in the 20 tissue processing?</p> <p>21 A Absolutely.</p> <p>22 Q In which foreign particulate matter can be 23 introduced into the specimens, and not just on the 24 surface of the block, but embedded in the block.</p> <p>25 You are aware of that, correct?</p>
<p style="text-align: right;">Page 187</p> <p>1 dependent, as I stated in the last sentence.</p> <p>2 Q Okay. Right. Do the animal studies as a whole 3 support your opinion on migration or detract from 4 your opinion on migration?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 A The animal studies as a whole, and I'm using 7 animals not including humans as animals here, to 8 me it's neutral. There is some evidence in 9 certain species, and I don't know the reproductive 10 systems of different types of rats versus rabbits 11 versus monkeys, for example, to speak at great 12 depth about it.</p> <p>13 But certainly it's more neutral for me in 14 terms of strength of evidence. Strength of 15 evidence is really the human studies.</p> <p>16 Q Do you see the human studies in the last 17 paragraph, that topic?</p> <p>18 A Yes.</p> <p>19 Q Do the human studies that you have looked at, 20 McDonald, Johnson, Heller, Henderson, do those 21 studies properly account for the fact that 22 laboratory processing of tissue specimens can 23 introduce particulate matter, not just on the 24 surface of the specimens, but deep within the 25 tissue?</p>	<p style="text-align: right;">Page 189</p> <p>1 MS. PARFITT: Objection to form.</p> <p>2 A I'm aware that if the standard operating 3 procedures are being followed, that introduction 4 that you spoke of of foreign material, let's just 5 say, can be absolutely minimized.</p> <p>6 Q If your testimony is that it could be minimized, 7 can it be eliminated?</p> <p>8 A I would say that, yes. If you followed the 9 correct protocols you could absolutely eliminate. 10 And, you know, for both it would be easier in some 11 circumstances to eliminate it than other 12 circumstances.</p> <p>13 But if you followed the standard operating 14 procedures faithfully, you could probably 15 eliminate that exposure.</p> <p>16 Q Is that standard operating procedure? Are labs 17 processing tissue specimens in a completely 18 sterile particulate-free environment, is that your 19 testimony?</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 A I can't speak to how these studies were performed.</p> <p>22 Q I'm asking about your experience at Komen.</p> <p>23 A Okay. It is not at Komen. They fund the tissue 24 bank. We do not, nor is it written in the 25 protocol, nor do we advertise ourselves as working</p>

<p style="text-align: right;">Page 190</p> <p>1 in a sterile environment.</p> <p>2 Q Does any gynecologic pathologist that processes</p> <p>3 tissue specimens to make diagnoses or make other</p> <p>4 commentary prognosis on the tissue or the tumor,</p> <p>5 is any gynecologic pathologist processing these</p> <p>6 specimens in a particulate-free sterile</p> <p>7 vacuum-hooded environment, is that happening?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 A I can't speak to what happens clinically. I am</p> <p>10 not in the gross room. I'm not a gynecologic</p> <p>11 pathologist.</p> <p>12 Q Do you agree that if there were particulate in a</p> <p>13 human tissue invivo that there would be biological</p> <p>14 reaction to that particle?</p> <p>15 A I think that question is too general for me to</p> <p>16 answer.</p> <p>17 Can you be more specific?</p> <p>18 Q I don't think so.</p> <p>19 A Can you restate?</p> <p>20 Q Do you know, I mean, is this something that is</p> <p>21 outside of your expertise? If you don't know, you</p> <p>22 can answer that way.</p> <p>23 Do you know if foreign particulate is</p> <p>24 introduced into tissue invivo, will a foreign</p> <p>25 particle cause a biological reaction?</p>	<p style="text-align: right;">Page 192</p> <p>1 introduction of this foreign object.</p> <p>2 Q With respect to the 2019 McDonald study, do you</p> <p>3 see that reference at the bottom of Page 13?</p> <p>4 A Yes.</p> <p>5 Q That is one of the papers we talked about earlier</p> <p>6 that was authored by experts for the plaintiffs.</p> <p>7 Do you recall that?</p> <p>8 A Yes, I recall that.</p> <p>9 MR. JAMES: I will mark McDonald as</p> <p>10 Exhibit 14.</p> <p>11 (EXHIBIT NUMBER 14 WAS MARKED FOR</p> <p>12 IDENTIFICATION.)</p> <p>13 A Okay.</p> <p>14 Q And you recall reviewing this study for the</p> <p>15 preparation of your report, correct?</p> <p>16 A Yes, I do.</p> <p>17 Q Did you have any concerns with the study?</p> <p>18 Did you identify any weaknesses in it?</p> <p>19 MS. PARFITT: Objection. Compound.</p> <p>20 You can answer.</p> <p>21 Q Either one. Give me a concern or a weakness.</p> <p>22 A As an epidemiologist, I would worry about a sample</p> <p>23 size of five. I would consider that a limitation.</p> <p>24 Q Do you have any concerns with how the cases were</p> <p>25 selected?</p>
<p style="text-align: right;">Page 191</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 A Again, that question is absolutely broad. You</p> <p>3 know, when you say introduced invivo, are you</p> <p>4 talking about, like, a cell line? When you talk</p> <p>5 about a foreign object being introduced, you know,</p> <p>6 any kind of reaction?</p> <p>7 It's way too broad for me to say yes, no, or</p> <p>8 even maybe.</p> <p>9 Q So my question is not about invitro. It's not</p> <p>10 about cell studies. It's about invivo. In a</p> <p>11 living human being if foreign particles such as</p> <p>12 talc were getting into tissue, would there be</p> <p>13 evidence of biological reaction either through</p> <p>14 granulomatous reaction, through macrophages?</p> <p>15 Do you know that? Is that outside of your</p> <p>16 expertise?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 A I know what I know from reading the literature and</p> <p>19 from understanding just basic biology that what</p> <p>20 you are alluding to from what I can gather from</p> <p>21 your question is host response, like, the actual</p> <p>22 person, the host's response to this foreign body.</p> <p>23 That may differ for everybody. You can't</p> <p>24 give a one size fits all and say a hundred percent</p> <p>25 everybody would have some sort of reaction to this</p>	<p style="text-align: right;">Page 193</p> <p>1 A I'm going to review that. No, I don't believe so.</p> <p>2 They were clear. They all had a history carcinoma</p> <p>3 ovarian cancer and history of perineal talc use.</p> <p>4 Q So the exposure status was known to the</p> <p>5 researchers, correct?</p> <p>6 A Correct.</p> <p>7 Q Is that a flaw?</p> <p>8 A No. In the manner of, you know, you don't know</p> <p>9 necessarily who on the research team did the</p> <p>10 patient selection.</p> <p>11 If they are all being, I mean, I'm not sure</p> <p>12 how else you would get this tissue. So I don't</p> <p>13 see that necessarily as a flaw. They describe</p> <p>14 what they did.</p> <p>15 That is the idea behind material and methods.</p> <p>16 Could somebody reproduce this work?</p> <p>17 Q Turn to Page 591 of the article. The second page.</p> <p>18 A Yes.</p> <p>19 Q The bottom full paragraph starts with "Tissue</p> <p>20 digestion."</p> <p>21 Do you see that?</p> <p>22 A I do.</p> <p>23 Q So in this paragraph they are talking about tissue</p> <p>24 digestion.</p> <p>25 A Okay.</p>

<p style="text-align: right;">Page 194</p> <p>1 Q And I want you to look at that last sentence for 2 me. 3 A Okay. 4 Q It says, "Also, even though the authors stated 5 they used talc-free gloves, contamination from 6 laboratory processing sources outside the authors' 7 own environment could have also played a role, 8 given the widespread occurrence of talc in many 9 settings." 10 A I see that. 11 Q They are talking about the Heller study. That is 12 cited in your report. 13 Do you recall that study? 14 A Yes. 15 Q Again, Heller is the study that looked at particle 16 burden in both users and non-users. They found 17 talc in everyone. 18 Do you recall that? 19 A I do. 20 Q So this last sentence certainly supports the 21 notion that processing labs are not particle free 22 environments, correct? 23 MS. PARFITT: Objection. 24 A They are stating here that, yes, there could be 25 unassessed exposures including, I guess it's a</p>	<p style="text-align: right;">Page 196</p> <p>1 that study to see if they had negative controls. 2 Q Do you think negative controls is a necessary 3 component of a study like this? 4 A It really depends on the overall hypotheses. 5 Q Okay. 6 A Let me see what they were actually trying to test. 7 Q I was asking in general. 8 A In general, no. There can be study designs that 9 have no controls. We have case only studies. We 10 have interventional only arms of other kinds of 11 studies. 12 Q So if the Johnson study did not use negative 13 controls that would not be methodologically 14 concerning to you? 15 MS. PARFITT: Objection. 16 A No, it would not. Based on as long as it was 17 disclosed. And, again, it's really based on what 18 is the primary hypothesis that they are trying to 19 examine. 20 Q And for Johnson and for McDonald, again, did you 21 see whether or not methodologically they 22 sufficiently accounted for particulate introduced 23 during the processing of the tissue specimens? 24 A Looking at McDonald, you know, they did talk about 25 what they did to, you know, try to -- this is on</p>
<p style="text-align: right;">Page 195</p> <p>1 little bit up farther, contamination from 2 laboratory or other sources. 3 Q Got it. And you said your own lab does not 4 advertise itself as a particle free environment? 5 A Correct. Yes. 6 Q Do you know if they used any negative controls in 7 the study? 8 A I would have to read here. I'm not seeing that 9 they introduced any negative controls. 10 Q The Johnson 2020 study that you also cite in the 11 same passage, do you know if they used negative 12 controls in that study? 13 A Let me say for McDonald, Page 592, they did 14 actually provide a set of non-exposed controls for 15 the five patients in the case series. Six 16 patients, from six patients with ovarian 17 carcinoma, part of a large case control study. 18 So they did use, it looks like, controls that 19 at least had reported talc use. 20 Q Do you know if, the question I just asked, do you 21 know if they used negative controls in the Johnson 22 study? 23 A I do not. They used eleven randomly selected 24 patients as part of that study. That was to look 25 at particle counts. No. I would have to look at</p>	<p style="text-align: right;">Page 197</p> <p>1 Page 592. Let's see. That is their second 2 paragraph there. 3 They talk about removing surface 4 contamination. They talk about different ways 5 that they washed, you know, surfaces in distilled, 6 deionized water and so on. 7 They stored them in closed containers, so 8 they did make an effort to keep out any other 9 contamination. 10 For Johnson I would have to pull the paper. 11 Q Let me give you the Johnson paper. 12 A Okay. 13 Q We will mark that as Exhibit 15. 14 (EXHIBIT NUMBER 15 WAS MARKED FOR 15 IDENTIFICATION.) 16 Q My question for both McDonald and Johnson is not 17 really whether they reported having taken steps to 18 attempt to control, it's whether you have an 19 opinion on whether the steps reported in the 20 studies are sufficient to control for particulate 21 that can be introduced during the tissue 22 processing? 23 Do you have an opinion on that? 24 A My opinion, and this is without looking at the 25 Johnson paper carefully, is that because these</p>

<p style="text-align: right;">Page 198</p> <p>1 were published in peer reviewed journals by 2 individuals with expertise in these types of, you 3 know, bio specimen handling and laboratory 4 processing, that if they made it through peer 5 review and addressed the concerns that the 6 reviewers potentially brought up about all of the 7 different methods used in the study, that I would 8 be comfortable that the appropriate steps were 9 taken.</p> <p>10 Q Okay. Because it went through the peer review 11 process?</p> <p>12 A Yes, because it went through the peer reviewed 13 process.</p> <p>14 Q Do you have that standard for any article that is 15 in a peer review journal, that if it made it 16 through a peer review that you can be happy or 17 comfortable with the propositions set forth in 18 that article?</p> <p>19 MS. PARFITT: Objection to form.</p> <p>20 A Asking about any article in the whole wide world 21 of literature, I would still want to review 22 everything individually myself to the best of my 23 understanding before I said, like, yes.</p> <p>24 Just because it made it through peer review 25 it does not mean that it is a hundred percent</p>	<p style="text-align: right;">Page 200</p> <p>1 But it would have to be pretty heavy 2 contamination from what I'm looking at here. 3 Again, the fact that they have provided enough 4 detail to make it to peer review, that they have 5 done their due diligence, and the fact that they 6 said here on Page 529 that the measurements were 7 essentially consistent and reproducible, this is 8 talking about what they found in the Johnson & 9 Johnson and the Caswell-Massey talcum powders.</p> <p>10 The fact that they also have some, it's an 11 internal control not in the way that we are 12 talking about controls meaning separate cases, but 13 oftentimes things like replication of your own 14 findings, you will do things in triplicate, for 15 example. That another type of internal control.</p> <p>16 And that would suggest to me that the 17 conclusions of the study are supported by the 18 results.</p> <p>19 Q You are aware that in 2010 the IARC Monograph that 20 was published, they concluded that the evidence 21 for retrograde transfer of talc to the ovaries in 22 normal women was weak.</p> <p>23 You are aware that they made that conclusion?</p> <p>24 A I would like to see the whole statement.</p> <p>25 Q Let me ask you this. Do you believe that the</p>
<p style="text-align: right;">Page 199</p> <p>1 perfect. We all find little errors in our own 2 reports and things as we go through them.</p> <p>3 But overall with the general methodology with 4 the methods proposed having a peer reviewed 5 publication increases my confidence of the study 6 findings.</p> <p>7 Q Sure. And I hear that. Are you using the fact 8 that Johnson and Godleski's articles, that they 9 went through the peer review process, are you 10 relying on that to reach the opinion that they did 11 adequately control for the introduction of 12 particulate matter in the tissue processing?</p> <p>13 MS. PARFITT: Objection to form. Asked 14 and answered.</p> <p>15 A I am also relying on my review of it as well.</p> <p>16 Q Do you think that the particles that they are 17 reporting finding in their literature could be 18 from contaminate introduced during tissue 19 processing?</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 Q Do you think it's possible?</p> <p>22 MS. PARFITT: Same objection.</p> <p>23 A I think it's possible that they were from the 24 initial use at various points in life of talcum 25 powder and it could also be from introduced.</p>	<p style="text-align: right;">Page 201</p> <p>1 evidence for retrograde transport of talc to the 2 ovaries in normal women is weak?</p> <p>3 A No.</p> <p>4 Q You cite the Keskin study on Page 14. I will mark 5 that as Exhibit 16.</p> <p>6 (EXHIBIT NUMBER 16 WAS MARKED FOR 7 IDENTIFICATION.)</p> <p>8 A Yes.</p> <p>9 Q Turn to Page 929.</p> <p>10 A I'm looking to see where I cited it. Okay. I'm 11 sorry.</p> <p>12 Q Page 929. The bottom full paragraph on the left 13 column beginning with the word "Salazar."</p> <p>14 A Yes.</p> <p>15 Q At the end of that paragraph --</p> <p>16 MS. PARFITT: Did you hand me a copy of 17 that? Thank you.</p> <p>18 Q At the bottom of that paragraph the authors say, 19 "Therefore, this study did not demonstrate an 20 association between talc application and 21 peritoneal/ovarian cancer."</p> <p>22 Do you see that?</p> <p>23 A I do.</p> <p>24 Q You did not note that in your report?</p> <p>25 A I don't know what that is referring to so I need</p>

<p style="text-align: right;">Page 202</p> <p>1 to look at it.</p> <p>2 Q That is a fairly significant statement in the</p> <p>3 article, correct?</p> <p>4 A Right now the way I'm reading it, that is in</p> <p>5 reference to BRCA1 positive women. So I need to</p> <p>6 take a deeper look into that.</p> <p>7 Seems to me in this they are comparing, you</p> <p>8 know, the work they presented here that was in a</p> <p>9 rat model to something that was seen in humans, in</p> <p>10 women who underwent a prophylactic oophorectomy.</p> <p>11 And so they are trying to say what they say</p> <p>12 in rats did not support the findings in these</p> <p>13 women. And, therefore, the study does not</p> <p>14 demonstrate this association.</p> <p>15 But, again, we are comparing rats to humans.</p> <p>16 As I mentioned earlier, you know, not knowing the</p> <p>17 details about rat physiology, I would not</p> <p>18 necessarily expect the findings in rats to apply</p> <p>19 to the findings in humans.</p> <p>20 So if I'm interpreting this paragraph</p> <p>21 correctly, it does not seem like a very strong</p> <p>22 statement because, again, it's apples to oranges</p> <p>23 versus apples to apples.</p> <p>24 Q You do cite Keskin in your report, correct?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 204</p> <p>1 rats, what does talc do? That is a very brief</p> <p>2 summary of it.</p> <p>3 And, you know, what they conclude is that it</p> <p>4 has unfavorable effects. There is no real talk of</p> <p>5 humans about it at all, other than trying to</p> <p>6 extend it to this other study of BRCA1 positive</p> <p>7 women.</p> <p>8 So I don't see where the connection really is</p> <p>9 there.</p> <p>10 Q With respect to the Mandarino study, I will mark</p> <p>11 that as Exhibit 17.</p> <p>12 (EXHIBIT NUMBER 17 WAS MARKED FOR</p> <p>13 IDENTIFICATION.)</p> <p>14 Q Did you have any concerns with that study?</p> <p>15 MS. PARFITT: Objection to the question.</p> <p>16 Somewhat broad.</p> <p>17 Q Did you identify any flaws in that study?</p> <p>18 A Let me take a look.</p> <p>19 MS. PARFITT: Objection to the question.</p> <p>20 You can answer.</p> <p>21 A Sure. No, I don't have any particular concerns</p> <p>22 other than the fact that, again, this is a murine</p> <p>23 ovarian cell model versus in a human. It's just a</p> <p>24 different type of study.</p> <p>25 Q Was the gene expression profiling unique to talc?</p>
<p style="text-align: right;">Page 203</p> <p>1 Q You cite it for the proposition, right, that the</p> <p>2 preliminary results showed that talc given</p> <p>3 inter-vaginally daily for three months had</p> <p>4 unfavorable effects on the female genital system.</p> <p>5 That is what you put into your report,</p> <p>6 correct?</p> <p>7 A Yes.</p> <p>8 Q You don't put the corollary that the authors</p> <p>9 actually concluded that the study did not</p> <p>10 demonstrate an association between talc</p> <p>11 application and peritoneal/ovarian cancer.</p> <p>12 And my question is why would you not have</p> <p>13 given a balanced discussion of this article in</p> <p>14 your report?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 A I feel actually like I do. I just say preliminary</p> <p>17 results and then they had unfavorable effects.</p> <p>18 I guess I should have said on the rat genital</p> <p>19 system similar to that of a foreign body reaction</p> <p>20 or infection.</p> <p>21 And to me this jump into, you know, the</p> <p>22 effects in BRCA1 positive women, that discussion</p> <p>23 is maybe an extension of the findings. But the</p> <p>24 actual, I think, hypothesis or what they were</p> <p>25 really trying to study here was introduced into</p>	<p style="text-align: right;">Page 205</p> <p>1 A I see the results of the gene expression. I don't</p> <p>2 really see what the results are. Talc and</p> <p>3 estrogen. I think that is -- maybe not.</p> <p>4 Q Do you have the expertise to evaluate this study?</p> <p>5 A I do. I have a fair amount of work looking at</p> <p>6 gene expression data, mutational profiling and</p> <p>7 those sorts of thing.</p> <p>8 Q Were the dosages in that study appropriate to make</p> <p>9 any comment on the hypotheses offered?</p> <p>10 A I'm not an expert in toxicology. I could not say</p> <p>11 per dose, no.</p> <p>12 Q I will show you the Fletcher study.</p> <p>13 A Okay.</p> <p>14 (EXHIBIT NUMBER 18 WAS MARKED FOR</p> <p>15 IDENTIFICATION.)</p> <p>16 Q This is Exhibit 18.</p> <p>17 A Yes.</p> <p>18 Q This is another one of the studies that have been</p> <p>19 co-authored by a plaintiffs' expert, is that</p> <p>20 correct?</p> <p>21 A Yes.</p> <p>22 Q Did you examine the abstracts for this study</p> <p>23 before it was published?</p> <p>24 A No.</p> <p>25 Q Do you know if the cell lines they used are good</p>

<p style="text-align: right;">Page 206</p> <p>1 models for ovarian cancer?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 Q Is that within your expertise?</p> <p>4 A No. I would not characterize cell line as good,</p> <p>5 bad, or otherwise.</p> <p>6 Q Do you know if the SNPs that Dr. Saed tested have</p> <p>7 been correlated with ovarian cancer?</p> <p>8 A SNP, single-nucleotide polymorphisms. Let me see</p> <p>9 what they did in this study. I'm not sure how</p> <p>10 they selected those particular genes or SNPs.</p> <p>11 Certainly, I mean, MPO has been associated</p> <p>12 with several different cancer types.</p> <p>13 Q I am sorry. Do you know if they are associated</p> <p>14 with ovarian cancer?</p> <p>15 A Specifically, no. I didn't do a review about the</p> <p>16 genetics of ovarian cancer.</p> <p>17 Q Do you know if the dosages that Dr. Saed used in</p> <p>18 this study are comparable in any way to the dose</p> <p>19 that would be imparted upon a woman who uses</p> <p>20 perineal talc?</p> <p>21 MS. PARFITT: Objection. Asked and</p> <p>22 answered.</p> <p>23 A No. I don't know what the actual dose used here</p> <p>24 was in terms of experientially what it would be</p> <p>25 compared to what a woman uses.</p>	<p style="text-align: right;">Page 208</p> <p>1 not tell you. I have no opinion on that.</p> <p>2 Q As a scientist who works in the field of female</p> <p>3 cancers, that is not something that you are aware</p> <p>4 of, correct?</p> <p>5 You have not heard before that CA-125 has a</p> <p>6 role in ovarian cancer causation or initiation,</p> <p>7 correct?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 A Initially CA-125 was being used as a biomarker</p> <p>10 detecting ovarian cancer. The hope was that it</p> <p>11 would be a marker of early detection. That didn't</p> <p>12 pan out.</p> <p>13 So you could say as an extension from that,</p> <p>14 that it could be a marker of early carcinogenesis.</p> <p>15 That would imply that it's in the pathway of</p> <p>16 carcinogenesis.</p> <p>17 Q As a scientist sitting here today, do you have an</p> <p>18 opinion that CA-125 has a role in cancer, ovarian</p> <p>19 cancer causation or initiation?</p> <p>20 MS. PARFITT: Objection. Asked and</p> <p>21 answered.</p> <p>22 A No. I do not have an opinion as to whether it has</p> <p>23 a role in causation or initiation based on the</p> <p>24 data that I have reviewed.</p> <p>25 MR. JAMES: Let's take a quick break.</p>
<p style="text-align: right;">Page 207</p> <p>1 Q Do you believe that CA-125 has a role in ovarian</p> <p>2 cancer initiation?</p> <p>3 A At this point in time the only evidence I've seen</p> <p>4 in terms of it being used as anything is as a</p> <p>5 marker for disease progression or recurrence.</p> <p>6 I have not seen it used yet in initiation.</p> <p>7 Certainly the gene that is associated with that</p> <p>8 marker has been studied.</p> <p>9 Q The bottom line is you are not aware of any</p> <p>10 evidence that CA-125 has a role in ovarian cancer</p> <p>11 causation initiation, correct?</p> <p>12 MS. PARFITT: Objection to form.</p> <p>13 A CA-125 is like a downstream product of a</p> <p>14 particular gene. So whether that gene -- which I</p> <p>15 would have to go and look -- has an association</p> <p>16 with the initiation of cancer, I don't know.</p> <p>17 But CA-125 is just a biomarker. It is not,</p> <p>18 in and of itself, a gene.</p> <p>19 Q I'm sorry if my question suggested that it was.</p> <p>20 A Okay.</p> <p>21 Q I didn't mean to. I don't think I said gene.</p> <p>22 But if I did, just to be clear, is there</p> <p>23 evidence that CA-125 has any role in ovarian</p> <p>24 cancer causation or initiation?</p> <p>25 A I did not examine that research question. I could</p>	<p style="text-align: right;">Page 209</p> <p>1 (OFF RECORD AT 2:41 P.M.)</p> <p>2 (AT THIS TIME A SHORT RECESS WAS HELD OFF</p> <p>3 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS</p> <p>4 WERE HAD:)</p> <p>5 (ON RECORD AT 2:50 P.M.)</p> <p>6 BY MR. JAMES:</p> <p>7 Q Dr. Cote, let's talk about inflammation. Okay?</p> <p>8 A Okay.</p> <p>9 Q Do you believe chronic inflammation is a mechanism</p> <p>10 for the talc ovarian cancer association that you</p> <p>11 allege, do you believe that that is the mechanism</p> <p>12 that you are relying on?</p> <p>13 A I believe that that is one potential mechanism</p> <p>14 that makes the association between talc exposure</p> <p>15 and ovarian cancer biologically plausible.</p> <p>16 Q On Page 6 of your report you said in the second</p> <p>17 paragraph that starts with "Published studies," do</p> <p>18 you see that?</p> <p>19 A Yes.</p> <p>20 Q You said that "The putative mechanism is the</p> <p>21 inflammatory response."</p> <p>22 Do you see that?</p> <p>23 A Uh-huh.</p> <p>24 Q By the word -- well, let me just read the full</p> <p>25 sentence.</p>

<p>Page 210</p> <p>1 "The putative mechanism is the inflammatory 2 response caused by the talcum powder, resulting in 3 chronic inflammation and oxidative stress, which 4 may initiate the carcinogenic process."</p> <p>5 Do you see that?</p> <p>6 A Yes.</p> <p>7 Q By the usage of the word "putative" there, in your 8 mind what level of scientific evidence exists for 9 that mechanism?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 You may answer.</p> <p>12 A Sure. So I would note that that is from the 13 executive summary so I don't have citations or 14 anything else built around the executive summary.</p> <p>15 So I would like us to go back to the section 16 where I talk about the different lines of evidence 17 that suggest that this is an inflammatory, kind of 18 a chronic inflammatory response as the biologic 19 mechanism I focused on in my work here, that was 20 to me the best evidence and the best explanation 21 for multiple lines of data.</p> <p>22 Q Do you consider chronic inflammation to be a 23 hypothesis, to be a theory, to be proven?</p> <p>24 How do you characterize that?</p> <p>25 A I think chronic inflammation with respect to</p>	<p>Page 212</p> <p>1 plausible? Whatever word you want to use.</p> <p>2 A Sure.</p> <p>3 Q How do you feel about the evidence to date?</p> <p>4 A I feel like --</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 A I feel like there is -- that the biologic 7 plausibility that talcum powder exposure leads to 8 chronic, among other things, chronic inflammation 9 and a host of different reactions, inflammatory 10 markers, kind of a cascade of effects that 11 ultimately leads to an environment where the 12 person is more susceptible to the development of 13 ovarian cancer.</p> <p>14 So it's a biologically plausible mechanism.</p> <p>15 It was, you know, the one that I found probably 16 the most evidence for.</p> <p>17 Is it proven? That I don't know. That was 18 not the question that I was being asked. My 19 question was, is there is causal association 20 between talc use and ovarian cancer. Biological 21 plausibility just one little spoke in the rest of 22 that wheel.</p> <p>23 Q Okay. Are there any other mechanisms, biological 24 mechanisms that you consider relevant to your 25 analysis of biologic plausibility other than</p>
<p>Page 211</p> <p>1 cancer is the hallmark of cancer.</p> <p>2 Q Let me be clear. With respect to the talc ovarian 3 cancer or claim, do you believe chronic 4 inflammation is the mechanism for talc to 5 allegedly cause ovarian cancer?</p> <p>6 In your mind is that hypotheses still, is it 7 a theory, is it scientifically proven?</p> <p>8 MS. PARFITT: Objection to the form as 9 framed.</p> <p>10 You can answer.</p> <p>11 A Yeah. Hypotheses to me is a single -- I'm going 12 to go through each. Hypotheses is just an 13 absolute, like, a single statement. And normally 14 we, as epidemiologists we state it as null. There 15 is no difference between two things.</p> <p>16 So a hypothesis is something that you build 17 research around.</p> <p>18 So the next was, I believe, you used theory?</p> <p>19 So --</p> <p>20 Q Yeah. I was not trying to use magic words.</p> <p>21 A Okay.</p> <p>22 Q I was trying to get your sense of do you feel like 23 it has been proven scientifically that talc 24 results in chronic inflammation that causes 25 ovarian cancer? Or do you feel like it's</p>	<p>Page 213</p> <p>1 chronic inflammation?</p> <p>2 A Chronic inflammation was the one that I focused on 3 primarily.</p> <p>4 Q I appreciate that. I'm not trying to be too 5 persistent here.</p> <p>6 A Okay.</p> <p>7 Q But when you come to trial will you be offering to 8 the jury another mechanism?</p> <p>9 Or is chronic inflammation the mechanism that 10 you intend to opine on?</p> <p>11 A Based on my readings to date, which may change if 12 more evidence is introduced, if more, you know, 13 primary literature develops in this area or in 14 other areas, I think it's, I would hold the right 15 to introduce other, you know, potential biological 16 mechanisms.</p> <p>17 At this point, based on the readings and the 18 evaluation I've done so far, my focus would be on 19 chronic inflammation.</p> <p>20 Q Do you believe that is the plausibility mechanism 21 or the plausible mechanism for all subtypes of 22 EOC?</p> <p>23 Did you consider plausibility by histotype?</p> <p>24 A I did not consider plausibility by histotype. I 25 considered just epithelial ovarian cancer kind of</p>

<p>Page 214</p> <p>1 as a whole.</p> <p>2 Q Did you cite to any study, or are you aware of any</p> <p>3 study showing inflamed ovarian tissue following</p> <p>4 perineal talc use?</p> <p>5 A How would you define inflamed ovarian tissue?</p> <p>6 Q Okay. Let me try to rephrase.</p> <p>7 A Yes.</p> <p>8 Q Are you aware of any study that shows an</p> <p>9 inflammatory process in gynecologic tissue</p> <p>10 following perineal talc use?</p> <p>11 A Let's look at what I have written. Actually I</p> <p>12 think there is a very good discussion of this as</p> <p>13 well in Health Canada. Maybe going to Health</p> <p>14 Canada is what we should do first.</p> <p>15 Q I appreciate that. But I'm asking you about a</p> <p>16 scientific study.</p> <p>17 Do you consider Health Canada to be a</p> <p>18 scientific study?</p> <p>19 A They were a large systematic review comprised of a</p> <p>20 bunch of different scientific studies even much</p> <p>21 larger in scope of what I have done here.</p> <p>22 If we want to go to my section on</p> <p>23 inflammation, we can do that. We can also look at</p> <p>24 the Health Canada one.</p> <p>25 Q Let me try to get back on track here. I'm going</p>	<p>Page 216</p> <p>1 that you are opining on, would it be visible?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 A I think it would be visible to, like, a pathologic</p> <p>4 examination of the tissue. Especially if you were</p> <p>5 basically taking slides and cuts of tissue you</p> <p>6 could identify things that are markers of</p> <p>7 inflammation like macrophages, infiltrating</p> <p>8 lymphocytes.</p> <p>9 That to me is evidence of chronic</p> <p>10 inflammation. And localized, as well, potentially</p> <p>11 to a certain tissue versus, like, chronic whole</p> <p>12 body inflammation.</p> <p>13 Q What study are you referring to?</p> <p>14 A Yeah. We can look at these. Some of these were</p> <p>15 in the Keskin. That was more looking at rats and</p> <p>16 noticed that there was this introduction into the</p> <p>17 foreign body. There are other cell lines. There</p> <p>18 are cancer cell lines that increase production of</p> <p>19 reactive oxygen species, which we know then</p> <p>20 facilitate kind of, again, this cascade effect of</p> <p>21 a lot of different processes that are associated</p> <p>22 with cancer initiation and progression. Things</p> <p>23 like cellular proliferation, differentiation of</p> <p>24 cells, cell signaling, and so forth.</p> <p>25 Those are, you know, in response these are</p>
<p>Page 215</p> <p>1 to have to ask the questions. If you don't</p> <p>2 understand the question, just tell me.</p> <p>3 A Okay.</p> <p>4 Q But are you aware of any study that demonstrates</p> <p>5 inflammation granulomatous reaction through the</p> <p>6 female reproductive tract following perineal talc</p> <p>7 use?</p> <p>8 A Again, I'm going to look at what I wrote in my</p> <p>9 report so that what I tell you is accurate. I</p> <p>10 want to be sure I don't conflate different studies</p> <p>11 in my mind.</p> <p>12 Q What page are you on?</p> <p>13 A I'm around Page 14. The bottom of Page 14.</p> <p>14 Q Let me ask you a different question. I think</p> <p>15 maybe my question is not clear.</p> <p>16 Is the type of inflammation that you are</p> <p>17 opining on for plausibility, is the type of</p> <p>18 inflammation you are opining on, would it be</p> <p>19 visible?</p> <p>20 MS. PARFITT: I have to object to that.</p> <p>21 I'm not sure I understand the question.</p> <p>22 Objection.</p> <p>23 A Visible to the human eye?</p> <p>24 Q To the human eye? To a gynecologic pathologist?</p> <p>25 Would this chronic inflammation mechanism</p>	<p>Page 217</p> <p>1 cell line studies. There is other work that</p> <p>2 suggests that talc actually attacks these</p> <p>3 macrophages because they are like a foreign body.</p> <p>4 Q So I appreciate that. I appreciate that is what</p> <p>5 you noted in the report.</p> <p>6 What I didn't see in the report and what I'm</p> <p>7 asking you if you know exists, do you know if</p> <p>8 there is any study out there that reports</p> <p>9 inflammation or granulomatous reaction in the</p> <p>10 reproductive tract or gynecologic tissue of a</p> <p>11 woman who used talc and got ovarian cancer?</p> <p>12 MS. PARFITT: Objection to the form.</p> <p>13 A Yeah. I don't know of a systematic study that has</p> <p>14 examined that question in that context. There are</p> <p>15 certainly studies that have shown that there is</p> <p>16 evidence of talc in the ovarian tissue.</p> <p>17 And we know that in the cell line studies</p> <p>18 that the, you know, exposure to talc increases all</p> <p>19 of these different reactive oxygen species that</p> <p>20 then go on and promote carcinogenesis.</p> <p>21 Q On Page 38 of your report when you are discussing</p> <p>22 plausibility you conclude with a statement in the</p> <p>23 last paragraph there -- I will wait for you to get</p> <p>24 there.</p> <p>25 You conclude with a sentence, "It is</p>

<p style="text-align: right;">Page 218</p> <p>1 well-accepted that inflammation contributes to the 2 initiation, development, and progression of 3 cancer, including ovarian cancer."</p> <p>4 Do you see where I read that?</p> <p>5 A Yes, I do.</p> <p>6 Q Is it your testimony, yes or no, is your testimony 7 that it is well-accepted that inflammation 8 contributes to the initiation of ovarian cancer?</p> <p>9 A Yes. And I think that the paper we talked about 10 earlier that is not cited here, correct, it was 11 the Johnson paper that I said was a replication 12 of, in African-American, of the Catherine Brieger 13 paper, the one I mentioned first, almost first 14 thing this morning.</p> <p>15 Q Brieger?</p> <p>16 A Brieger, that is it. That was one of the indices 17 that they built, was an inflammation index. I do 18 feel that the biologic plausibility suggests more 19 likely than not that this is a potential mechanism 20 for ovarian cancer initiation.</p> <p>21 Q Okay.</p> <p>22 A It's the biological mechanism. I'm not 23 necessarily stating it's causation.</p> <p>24 Q In your opinion, is it well-accepted that 25 inflammation causes ovarian cancer?</p>	<p style="text-align: right;">Page 220</p> <p>1 contributes to the initiation, development, and 2 progression of cancer, including ovarian cancer."</p> <p>3 A Yes.</p> <p>4 Q One of them is that it contributes to the 5 initiation of ovarian cancer.</p> <p>6 "Is well-accepted that inflammation 7 contributes to the initiation of ovarian cancer" 8 is that just a plausibility opinion, or are you 9 saying that that is well-accepted?</p> <p>10 A I'm saying that that is a plausibility opinion. 11 It is plausible. It is underneath the biologic 12 plausibility. It is the last sentence in that 13 section.</p> <p>14 And additionally, speaking more broadly, you 15 know, it's a seminal paper in cancer research. I 16 believe it was published in 2000. Inflammation is 17 one of the hallmarks of cancer. That is cancers 18 broadly.</p> <p>19 But I would not find, I have not found or 20 done an extensive literature search or systematic 21 review of every type of cancer and inflammation.</p> <p>22 Q Is pelvic inflammatory disease reliably associated 23 with ovarian cancer?</p> <p>24 A I did not study pelvic inflammatory disease 25 specifically with respect to ovarian cancer. I</p>
<p style="text-align: right;">Page 219</p> <p>1 A No. I did not say that it causes it. I said that 2 looking at the association between talc and 3 ovarian cancer, one of the potential biologic 4 mechanisms, and the mechanism that is focused on 5 here, is that it leads to chronic inflammation.</p> <p>6 And it's a, in my mind, a very biologically 7 plausible mechanism from -- you know, it's 8 multiple lines of evidence.</p> <p>9 We see there is evidence for retrograde 10 menstruation. We know that from an epidemiologic 11 standpoint, you know, evidence is stronger when 12 you have an open or patent reproductive tract. We 13 see stronger associations with exposure with talc.</p> <p>14 We see in, you know, the cell line studies 15 that exposure to talc in the cell lines initiates 16 a lot of mediators that then are known to be other 17 kind of hallmarks of cancer, like uncontrolled 18 growth and cellular proliferation, reduction of 19 apoptosis, which is cell death.</p> <p>20 Q Right. My question is really, really precise.</p> <p>21 A Okay.</p> <p>22 Q We have gone through many of the lines of evidence 23 that you just discussed.</p> <p>24 You have on Page 38 this statement and you 25 say "It is well-accepted that inflammation</p>	<p style="text-align: right;">Page 221</p> <p>1 have seen some studies that indicate it does 2 increase risk. PID is, I think, sometimes an 3 umbrella term. It has a lot of other benign 4 gynecologic conditions associated with it. They 5 are not necessarily all singular in nature.</p> <p>6 We did publish a study on this from AACEs. I 7 would have to go back to the paper and look at it 8 to see what the actual results were.</p> <p>9 Q Do you have an opinion sitting here today on 10 whether PID is reliably associated with ovarian 11 cancer? Yes or no?</p> <p>12 MS. PARFITT: Objection. Asked and 13 answered.</p> <p>14 A There is some evidence that suggests it is. PID 15 is difficult to define.</p> <p>16 Q Okay. Do you know if anti-inflammatories are 17 routinely prescribed as a means to reduce ovarian 18 cancer risk?</p> <p>19 Have you ever heard of that?</p> <p>20 A I do not believe that NSAIDs are routinely 21 prescribed in the general population to reduce 22 risk of ovarian cancer.</p> <p>23 Q Would you agree that not all inflammation leads to 24 cancer?</p> <p>25 A I would agree that there is acute inflammation for</p>

<p style="text-align: right;">Page 222</p> <p>1 like when you cut your finger or something like 2 that and, no, that would not lead to ovarian 3 cancer. There is acute and chronic. 4 Q Do you agree that not all chronic inflammatory 5 conditions lead to cancer? 6 MS. PARFITT: Objection to form. 7 A I can't speak to all forms of inflammation and all 8 forms of cancer and make a blanket statement. 9 I've not done that review. 10 Q Do you know if rheumatoid arthritis is linked to 11 cancer? 12 A I've not looked at that association before. 13 Q Cancer itself can cause inflammation itself, 14 correct? 15 MS. PARFITT: Objection to form. 16 A Cancer of what type? 17 Q Cancer, in general, can cause inflammation, 18 correct? 19 MS. PARFITT: Any cancer? Objection. 20 A Any cancer can cause any inflammation anywhere. I 21 can't really say yes or no to that statement. 22 It's too broad. 23 Q I did not understand because -- regardless. 24 Do you believe that cancer can cause 25 inflammation?</p>	<p style="text-align: right;">Page 224</p> <p>1 whether it's acute or chronic. 2 Q Are you aware of any study that associates the 3 histologic presence of chronic inflammation in the 4 female genital tract -- 5 A No. 6 Q -- with ovarian cancer? 7 A No. I have not researched that particular 8 question. 9 Q Have you looked at any literature on chronic tubal 10 injuries and whether those are associated with 11 ovarian cancer? 12 MS. PARFITT: Objection. Form. 13 A No, I've not examined chronic tubal injury and 14 inflammation. 15 Q The Savant article on Page 14 that you cite 16 regarding inflammation, I have one question. 17 A That is a review article. 18 Q You answered my question. That is just a review 19 article? 20 A I don't know if it's a systematic review or not. 21 What page? 22 Q Page 14. 23 A Reference number what? 24 MS. PARFITT: It's reference 67. 25 A Yes.</p>
<p style="text-align: right;">Page 223</p> <p>1 MS. PARFITT: Objection to form. 2 A I believe that yes, cancer, cancerous cells can 3 induce an immune response much like that of 4 inflammation. 5 Part of what cancer does, and this is another 6 hallmark of cancer, is that it evades the immune 7 system. 8 Q Are you aware of any gynecologic pathologist that 9 believes high grade serous cancer is correlated 10 with or associated with inflammation? 11 MS. PARFITT: Objection. Form. 12 A I have never had this discussion with the 13 gynecologic pathologists that I work with. So, 14 no, I am not aware. 15 Q Are you aware of any study that demonstrates an 16 association between the histologic presence of 17 inflammation and tubal injury? 18 MS. PARFITT: Could you repeat the 19 question? 20 Q Are you aware of any study that demonstrates an 21 association between tubal injury or chronic 22 inflammation in the tubes with ovarian cancer? 23 MS. PARFITT: Objection. Form. 24 A Yeah. I think I need that clarified. I mean, any 25 form of injury causes some level of inflammation</p>	<p style="text-align: right;">Page 225</p> <p>1 Q It's a review article? 2 A It is. 3 Q Your summary of the Savant article on Page 14 that 4 rolls to Page 15 in your report -- 5 A Yes. 6 Q -- is it fair to say you are providing a summary 7 of the article in those two sentences? 8 Am I understanding that correctly? 9 A Yes. 10 Q Are those your independent opinions, or are you 11 reporting on Savant? 12 A After reading Savant this is how I would summarize 13 the article by this team. It is probably a very 14 simplistic picture of what they actually included 15 in this review. 16 Q Did you look at the citing references in the 17 Savant article? Do you recall? 18 A At one point in time, sure. 19 Q Did you look to see if the citing references 20 supported the statement in the article? 21 A I believe there were several hundred citing 22 references. Yeah. There is over 231, so I did 23 not check every reference and make sure that they 24 matched, no. 25 Q With respect to the specific conclusion that -- I</p>

<p style="text-align: right;">Page 226</p> <p>1 believe you were quoting it or close to it on 13 2 with respect to the sentence that since talc is 3 not degradable by the body it inhibits the wound 4 healing process resulting in chronic inflammation. 5 That is a statement that comes from Savant? 6 A Yes. 7 Q Did you see if they cited any support for that 8 statement? 9 A I would have to look. Is the question -- that is 10 a two part thing. 11 Is the question that talc is not degradable? 12 Is that what is in question? 13 Or that by the fact that it is not degradable 14 and that it's essentially this foreign body that 15 remains present that it inhibits the wound healing 16 response? 17 Q If it's okay, we will just move on. 18 A Okay. 19 Q Next we will talk about Health Canada. 20 A All right. 21 Q With respect to the Health Canada screening 22 assessment, were you aware that that document 23 cites litigation reports from paid experts? 24 A Yes, I was. 25 Q Is that scientifically appropriate?</p>	<p style="text-align: right;">Page 228</p> <p>1 sentence, "The Health Canada assessment was on 2 talc alone without considering whether or not talc 3 contained asbestos." 4 Do you see that? 5 A Yes, I do. 6 Q Then on Page 15 under Systematic Reviews in the 7 second sentence you say, "Of note, this report 8 specifically assumed cosmetic-grade talc 'to be 9 asbestos free'." 10 Do you see that? 11 A Yeah. 12 Q I will mark Health Canada as Exhibit 19. 13 (EXHIBIT NUMBER 19 WAS MARKED FOR 14 IDENTIFICATION.) 15 Q In regard to your comments on the asbestos issue, 16 I want to turn your attention to Page 6. Excuse 17 me. It's Page 3. 18 MS. PARFITT: The report is the Health 19 Canada report? 20 MR. JAMES: Yes. 21 A Can you read the first line at the top of Page 3? 22 Q Sure. "To both." 23 A Okay. Perfect. 24 Q So we see here on Page 3 if you go down to the 25 bottom two paragraphs, Health Canada does include</p>
<p style="text-align: right;">Page 227</p> <p>1 MS. PARFITT: Objection. 2 A I think for the type of review that Health Canada 3 was doing, they were not trying to publish this as 4 peer review literature. 5 My understanding was that documents were 6 openly accepted by both sides. I think that for 7 the purposes of what they are trying to do here, 8 which is inform policy regarding human health, 9 that it would be appropriate. 10 Q Have you ever seen another regulatory document 11 from a body like Health Canada that cites paid 12 expert reports? 13 A I have never -- 14 MS. PARFITT: Objection to form. 15 A I have never looked at other types of health 16 reports from governments. 17 Q Did IARC cite reports from paid litigation 18 experts? 19 A I don't believe so. 20 Q Are you aware of whether any of the retained 21 experts for the plaintiffs had contact with Health 22 Canada about the screening assessment? 23 A Retained experts from the plaintiffs? Not to my 24 knowledge at the time that I'm reviewing this, no. 25 Q On Page 6 of your report you state in the last</p>	<p style="text-align: right;">Page 229</p> <p>1 a discussion here on the issue of asbestos, 2 correct? 3 MS. PARFITT: Where are you referring? 4 Q Sure. There are different grades of talc that 5 refer to the purity. 6 Do you see that? 7 A Yes. I do now. 8 Q In that paragraph there, in the paragraph that 9 starts with "There are," they refer to the USP 10 specifications, which I mentioned earlier today, 11 right? 12 A Yes. 13 Q They talk about how those require the absence of 14 asbestos, do you see that? 15 A I do. 16 Q Then you can also see in the next paragraph it 17 talks about historically contamination in talcum 18 powders, do you see that? 19 A Yes. 20 Q Let me fix that. Talc source materials. 21 Do you see that? 22 A Yes. 23 Q It says "Historically, some talc source materials 24 were contaminated with asbestos." Right? 25 A Yes.</p>

<p style="text-align: right;">Page 230</p> <p>1 Q Then if you look on the next page you can see the 2 next paragraph says, In Canada."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q So at the conclusion of those paragraphs the 6 Health Canada assessment says, "The cosmetic-grade 7 talc used in the health effect studies cited in 8 this assessment were considered to be free of 9 asbestos."</p> <p>10 Do you see that?</p> <p>11 A Yes.</p> <p>12 Q Is it proper to say that Health Canada did not 13 consider the issue of asbestos or assumed that the 14 products were asbestos free?</p> <p>15 A That is what they state here, yes. That is what I 16 state on Page 15 as well.</p> <p>17 It's not a direct quote, but assumed 18 cosmetic-grade talc to be asbestos free.</p> <p>19 Q It may be just a difference in terminology, but 20 when I looked at your use of the word "assumed" it 21 conveyed to me that Health Canada had not 22 addressed the issue.</p> <p>23 A Okay.</p> <p>24 MS. PARFITT: So what is the question?</p> <p>25 MR. JAMES: I'm asking it.</p>	<p style="text-align: right;">Page 232</p> <p>1 MS. PARFITT: Objection to form.</p> <p>2 A I think they are making a statement that what they 3 have considered in this review, or in this 4 statement, is talc that is free of asbestos.</p> <p>5 So the findings in this report are about 6 talc, not specifically about talc containing 7 asbestos.</p> <p>8 Q You acknowledge in your report that Health Canada 9 has considered the inhalation of talc powders, 10 correct?</p> <p>11 A Correct. That was not the focus of my review.</p> <p>12 Q Sure.</p> <p>13 On Page 16 you do note that Health Canada 14 considered inhalation, correct?</p> <p>15 A Yes. They included oral, dermal, inhalation and 16 perineal.</p> <p>17 Q You recognize that Health Canada does not find 18 that inhalation of talcum powders confers a cancer 19 risk, correct?</p> <p>20 MS. PARFITT: Objection to form.</p> <p>21 A Again, that was not the reason that I was reading 22 and focusing on Health Canada.</p> <p>23 But I do not identify that in my report, 24 correct.</p> <p>25 Q You understand that Health Canada has concluded</p>
<p style="text-align: right;">Page 231</p> <p>1 MS. PARFITT: Okay.</p> <p>2 Q If you look at this paragraph, Health Canada walks 3 through specifications for talcum powders, 4 correct?</p> <p>5 It goes through historical information, 6 correct?</p> <p>7 A Correct.</p> <p>8 Q And then it notes in the last paragraph that, "In 9 Canada, the Prohibition of Asbestos and Products 10 Containing Asbestos Regulations (updated 2018) 11 under CEPA prohibit asbestos above trace levels in 12 products available to consumers, including 13 cosmetics."</p> <p>14 A Uh-huh.</p> <p>15 Q They go on to say, "The cosmetic-grade talc used 16 in the health effect studies cited in this 17 assessment were considered to be free of 18 asbestos."</p> <p>19 Do you see that?</p> <p>20 A I do.</p> <p>21 Q So Health Canada here is making a qualitative 22 statement on whether or not cosmetic-grade talc is 23 free of asbestos, is that correct?</p> <p>24 MS. PARFITT: Objection.</p> <p>25 Q They are not simply assuming.</p>	<p style="text-align: right;">Page 233</p> <p>1 that the inhalation of talcum powders does not 2 confer a cancer risk, correct?</p> <p>3 MS. PARFITT: Objection to form.</p> <p>4 A Cancer risk, meaning lung cancer or meaning 5 ovarian cancer?</p> <p>6 Q Do you understand that Health Canada has concluded 7 that the inhalation of talcum powders does not 8 confer a risk of ovarian cancer?</p> <p>9 A Yes, I believe that.</p> <p>10 MS. PARFITT: Objection to form.</p> <p>11 A I believe the conclusions from Health Canada was 12 that it was just the association between perineal 13 talc and ovarian cancer that was the causal 14 association.</p> <p>15 Q When you say causal, and I saw it sort of 16 described two different ways in your report. I 17 think one time you quote their language where they 18 say indicative of causal.</p> <p>19 Do you remember that?</p> <p>20 A Sure.</p> <p>21 Q Another time in your report you say causal.</p> <p>22 Do you recognize a distinction between the 23 phrase indicative of causal and causal?</p> <p>24 A Perhaps indicative of causation or causal is not 25 as strongly stated as causal.</p>

<p style="text-align: right;">Page 234</p> <p>1 But essentially it still means the same to 2 me. The Health Canada report, that was based on 3 multiple lines of evidence. They went through a 4 lot of the Bradford Hill considerations. They 5 drew from multiple sources.</p> <p>6 As you mentioned, they had testimony from 7 plaintiffs and defendants in this case. And their 8 findings were that there was, it was at least 9 indicative of a causal association.</p> <p>10 Q You do appreciate that that is the phraseology 11 they used, indicative of a causal effect, is that 12 correct?</p> <p>13 A Perhaps. I mean, I did not read every single -- I 14 could not quote every single statement in this 15 report.</p> <p>16 To me indicative of causal association is a 17 causal association. It indicates a causal 18 association.</p> <p>19 Q Okay. With respect to inhalation, do you have the 20 opinion that inhalation of talcum powders can 21 cause cancer and ovarian cancer, or is that an 22 area on which you do not intend to opine?</p> <p>23 A That is an area I do not intend to opine.</p> <p>24 Q With respect to IARC, you state in your report on 25 Page 16 at the very bottom that you believe that</p>	<p style="text-align: right;">Page 236</p> <p>1 really I think that they only reviewed up until 2 about 2006.</p> <p>3 So they are missing right now about fifteen 4 years' worth of data, you know, from 2006 to, say, 5 2023, last year. So it's more of a limited review 6 because it's not considering all of the data that 7 we have accumulated over the last decade and a 8 half.</p> <p>9 Q Did IARC get it right in 2006 and publish in 2010? 10 Was the evidence at that time supportive of 2B?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 A I didn't ask myself that question, per se. I 13 mean, I think what was presented based off of my 14 reading was that they felt like that was, I 15 believe, a move up from their earlier report.</p> <p>16 They had moved from -- I'm not quoting it 17 probably correctly -- you know, from -- yeah. 18 They moved it from Group 3 to a Group 2B.</p> <p>19 So they saw enough evidence, again, this is a 20 comprehensive report, multiple lines of evidence, 21 that suggested that it should be a higher concern 22 for human health.</p> <p>23 Q Do you have an opinion on whether when IARC 24 conducted its review that 2B was the correct 25 classification?</p>
<p style="text-align: right;">Page 235</p> <p>1 Health Canada goes a step farther. 2 That is your terminology, right?</p> <p>3 A Yes.</p> <p>4 Q You believe Health Canada goes farther than IARC, 5 is that fair?</p> <p>6 A Yes, that is fair.</p> <p>7 Q And IARC in 2010 when they published their 8 Monograph went with 2B for perineal application of 9 talc and ovarian cancer, correct?</p> <p>10 A Yes.</p> <p>11 Q 2B is what? What is the terminology?</p> <p>12 A It is deemed possibly carcinogenic to humans.</p> <p>13 Q And so your testimony is that Health Canada has 14 gone causal.</p> <p>15 And so you are saying that they have gone 16 further than IARC. And so you recognize IARC did 17 not go causal, correct?</p> <p>18 A Correct. Health Canada, if we were going to use 19 the terminology that IARC uses, they would call 20 perineal use of talc as a Group 1 carcinogen with 21 respect to ovarian cancer.</p> <p>22 Q And just like Health Canada, your opinion goes 23 further than IARC, correct?</p> <p>24 A My opinion goes further than IARC because IARC is 25 limited, at least in this Monograph, to data</p>	<p style="text-align: right;">Page 237</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 Q Yes or no? Do you have an opinion?</p> <p>3 MS. PARFITT: Objection.</p> <p>4 A Yes. I believe that IARC and the methodology that 5 they used was sufficient to go with the Group B 6 classification.</p> <p>7 Q 2B?</p> <p>8 A 2B, yes.</p> <p>9 Q You also understand that IARC has never classified 10 the perineal use of talc as a Group 1 for ovarian 11 cancer, correct?</p> <p>12 A Yes. My understanding is that their Group 1 is 13 asbestos. That is a Group 1 carcinogen.</p> <p>14 Q You agree that IARC -- and I'm being very precise 15 with my language.</p> <p>16 A Yes.</p> <p>17 Q That the perineal use of talcum powders has never 18 been classified by IARC as a Group 2A, correct?</p> <p>19 MS. PARFITT: Objection.</p> <p>20 A I'm going to quote directly from my report here, 21 which is talking about talc. This is from the 22 2012 about talc that is, that forms fibers that 23 are asbestos in habit referred to as fibrous 24 talc.</p> <p>25 As we reviewed, that has been classified as a</p>

<p style="text-align: right;">Page 238</p> <p>1 Group 1 human carcinogen.</p> <p>2 Q Earlier today you told me that you were opining on</p> <p>3 the body of literature that assesses the</p> <p>4 relationship between talcum powders and ovarian</p> <p>5 cancer, correct?</p> <p>6 A Yes.</p> <p>7 Q That body of literature was assessed by the 2010</p> <p>8 IARC Monograph, correct?</p> <p>9 A Yes.</p> <p>10 Q The IARC 2012 Monograph did not assess the same</p> <p>11 body of literature that you were assessing in your</p> <p>12 litigation report, correct?</p> <p>13 MS. PARFITT: Objection. Form.</p> <p>14 A The same body of literature. I believe I included</p> <p>15 some of the literature.</p> <p>16 Q The IARC 2012 Monograph that you just referred to</p> <p>17 did not go through Gertig and Gates and Houghton</p> <p>18 or Cramer or Merritt or Ness or Mills or Cook or</p> <p>19 Chang?</p> <p>20 That is the body of literature on talc</p> <p>21 ovarian cancer, correct?</p> <p>22 The 2020 Monograph did not address that body</p> <p>23 of literature, correct?</p> <p>24 MS. PARFITT: Objection to form.</p> <p>25 A I can go back and review exactly what 2012</p>	<p style="text-align: right;">Page 240</p> <p>1 perineal talc used in humans, and less than</p> <p>2 sufficient in animals, correct?</p> <p>3 A Yes. I believe how it's stated, or how I have it</p> <p>4 stated here, is "evidence supporting risk to</p> <p>5 humans is limited, and evidence from animal models</p> <p>6 is lacking; however, it is a higher level of</p> <p>7 concern than Group 3," which says that it is "not</p> <p>8 classifiable as to their carcinogenicity to</p> <p>9 humans."</p> <p>10 Q Okay. You also note Group 4 in your report,</p> <p>11 correct?</p> <p>12 A Yes.</p> <p>13 Q Do you know if IARC still uses a Group 4?</p> <p>14 A I do not. I have not committed that to memory.</p> <p>15 Q If I tell you that Group 4 no longer exists, does</p> <p>16 that ring a bell?</p> <p>17 Do you have any familiarity with that?</p> <p>18 MS. PARFITT: Objection.</p> <p>19 A No, I do not.</p> <p>20 Q With regard to IARC's classification of limited</p> <p>21 evidence, you understand that they concluded then</p> <p>22 that chance bias and confounding could not be</p> <p>23 ruled out for the association between talc and</p> <p>24 ovarian cancer, correct?</p> <p>25 A Correct.</p>
<p style="text-align: right;">Page 239</p> <p>1 included in their epidemiologic studies if that is</p> <p>2 how we need to spend our time.</p> <p>3 Off the top of my head I can't say what</p> <p>4 studies were or were not included in there.</p> <p>5 Q Okay. The 2010 Monograph is the monograph that</p> <p>6 makes a classification on the perineal use of</p> <p>7 talcum powders, correct?</p> <p>8 A Yes.</p> <p>9 Q The perineal use of talcum powders is not the</p> <p>10 focus of the 2012 Monograph, is that fair?</p> <p>11 MS. PARFITT: Objection to form.</p> <p>12 A I would say that is fair, yes.</p> <p>13 Q IARC has never issued a Group 1 or a Group 2A</p> <p>14 classification for the perineal use of talc</p> <p>15 powders in ovarian cancer, correct?</p> <p>16 MS. PARFITT: Objection. Misstates the</p> <p>17 evidence.</p> <p>18 A The 2010 report is the conclusion that is focused</p> <p>19 on perineal use of talc-based powder as a Group 2B</p> <p>20 carcinogen.</p> <p>21 Q The 2B classification from IARC -- I understand</p> <p>22 you go further than IARC. We talked about that.</p> <p>23 A Yes.</p> <p>24 Q But for IARC, the 2B classification is that there</p> <p>25 is limited evidence for carcinogenicity of</p>	<p style="text-align: right;">Page 241</p> <p>1 Q Let's talk about the section of your report on</p> <p>2 meta-analysis. I show that is Page 17.</p> <p>3 A Yes.</p> <p>4 Q Just to be fundamentally clear, it's titled</p> <p>5 Meta-analysis. You conclude with a Table 3,</p> <p>6 correct?</p> <p>7 A Yes.</p> <p>8 Q You have input into that table both O'Brien 2020</p> <p>9 and Terry 2013, correct?</p> <p>10 A Yes, that is correct.</p> <p>11 Q Just to be absolutely clear, those two are pooled</p> <p>12 analysis and not meta, is that correct?</p> <p>13 A Yes.</p> <p>14 Q Without getting into the details, there is an</p> <p>15 epidemiologic difference in those two study</p> <p>16 designs, correct?</p> <p>17 A Yes.</p> <p>18 Q With respect to O'Brien, this was the 2020 pooled</p> <p>19 analysis of the four cohort studies, correct?</p> <p>20 A Yes.</p> <p>21 Q Let's mark that as Exhibit 20.</p> <p>22 (EXHIBIT NUMBER 20 WAS MARKED FOR</p> <p>23 IDENTIFICATION.)</p> <p>24 Q You can just use your copy, too.</p> <p>25 A Okay.</p>

<p style="text-align: right;">Page 242</p> <p>1 Q Putting aside whether or not you agree with 2 O'Brien, the conclusion in the abstract is that, 3 "In this analysis of pooled data from women in 4 four U.S. cohorts, there was not a statistically 5 significant association between use of powder in 6 the genital area and incident ovarian cancer," 7 correct?</p> <p>8 A That is what their conclusion states, yes.</p> <p>9 Q They also comment in this paper that there was no 10 dose response, correct?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 A Yes. I believe that that is part of their 13 conclusions.</p> <p>14 Q Okay. Again, setting aside whether you agree or 15 disagree, on Page 56 they offer a discussion 16 section, the first paragraph.</p> <p>17 A Yes. I see where you are at.</p> <p>18 Q Okay. They say, "There were no clear 19 dose-response trends for duration and frequency of 20 powder use..." Correct?</p> <p>21 A Yes, that is what they say.</p> <p>22 Q On Page 50, the page after the abstract, in the 23 second paragraph they are talking about case 24 control studies.</p> <p>25 Then they say, "However, these findings may</p>	<p style="text-align: right;">Page 244</p> <p>1 Q Do you believe that the O'Brien paper, the overall 2 finding of the O'Brien paper, supports your 3 causation opinion, or just the findings on patent 4 reproductive tracts that supports your opinion?</p> <p>5 A It is not my overall causation. My overall 6 causation is not supported based on one study.</p> <p>7 Overall causation is based on multiple lines. 8 Biologic plausibility. Consistency. Strength of 9 the association.</p> <p>10 Overall, yes, I think the O'Brien paper and 11 these cohort studies, despite some limitations 12 that are inherent to cohort studies, particularly 13 of a disease of ovarian cancer which is a later 14 onset disease, still support the overall 15 association findings that there is an association 16 between risk of -- or I'm sorry -- between the use 17 of perineal talcum powder, genital talcum powder, 18 and ovarian cancer.</p> <p>19 Q Do you have the opinion that all of the cohort 20 studies demonstrate an association, or only three 21 of the studies demonstrate an association?</p> <p>22 A I'm of the opinion that one of the studies, in 23 particular, the Sister Study, has serious issues 24 at least in the initial, in particular in the 25 initial analysis with how they obtained the</p>
<p style="text-align: right;">Page 243</p> <p>1 be affected by recall bias and the recent surge in 2 talc-related lawsuits and media coverage."</p> <p>3 Do you see that?</p> <p>4 A Yes, I do.</p> <p>5 Q In the last sentence the O'Brien authors say, 6 "Thus, it is crucial to evaluate the talc-ovarian 7 cancer association using prospective data."</p> <p>8 Did I read that last sentence correctly?</p> <p>9 A You read that last sentence correctly.</p> <p>10 Q So at least the O'Brien authors are affirming that 11 it is crucial to evaluate this association with 12 prospective cohort data, correct?</p> <p>13 A It appears to be their belief, but they are the 14 ones writing the paper.</p> <p>15 Q Yes. I understand. Let me just say, you disagree 16 with that last sentence, is that correct, that I 17 just read?</p> <p>18 A I think cohort data still has a place and I -- not 19 to jump ahead, I think it does support an 20 association.</p> <p>21 So I think it is crucial to build evidence 22 where we can. Whether that evidence supports or 23 not the primary hypotheses that talc use is 24 associated with ovarian cancer, we should look at 25 all data available.</p>	<p style="text-align: right;">Page 245</p> <p>1 exposure information. There was a large degree of 2 misclassification, which they recognized, and it 3 was based on the timeframe that they were asking 4 about the talcum powder usage.</p> <p>5 It was drastically lower than any other 6 published case control or cohort study that I saw. 7 So I feel like for the purposes even of this 8 review or this meta-analysis, that that study 9 should have been excluded on that basis.</p> <p>10 Q Okay. In your report I think I saw, I could be 11 wrong, I thought I saw a couple conflicting 12 statements where at one point you said the four 13 cohort studies support an association, and then at 14 one point you said three.</p> <p>15 Are you taking a position that the 16 Sister Study supports an association or does not 17 support an association?</p> <p>18 A The Sister Study on its own does not support an 19 association based on the estimate provided in this 20 meta-analysis. I'm not talking about updated data 21 when they went back later and asked about the age 22 range of usage of being ten to thirteen, which 23 almost doubled their exposures.</p> <p>24 All three of the other analyses in here, all 25 individually if we look -- we should look so I'm</p>

<p style="text-align: right;">Page 246</p> <p>1 not just stating different. Perhaps it is here. 2 I think the other three studies individually 3 all provide some evidence that supports a positive 4 association. 5 Q The terminology "positive association" to you 6 means that it's more than one and it does not 7 matter if it crosses one, is that correct? 8 A At this point that is how I would define a 9 positive association. 10 Q So for you, statistical significance in these 11 studies does not prevent you from saying that they 12 reflect a positive association, is that? 13 MS. PARFITT: Object to the form. 14 A Correct. I would say that there is a positive 15 association. I would not say that there is a 16 statistically significant association. 17 A positive association could still be 18 important clinically. It could still be important 19 on a population level. Statistical significance 20 is really talking about, you know, a statistical 21 test. 22 Q But it is a test that is meant methodologically to 23 indicate when a certain result can be trusted. I 24 know you may not agree with my terminology. 25 But it's meant to indicate when a result can</p>	<p style="text-align: right;">Page 248</p> <p>1 positive, cross one, correct? 2 A Correct. But that can be for various reasons. 3 And one of the things that you can use when you 4 look at the confidence intervals, that gives you 5 some idea about just the sample size. 6 Whereas a P value does not give you any 7 additional information. 8 Q So for purposes of your opinion here, whether or 9 not a study presents an association that crosses 10 one, or whether or not a study has a statistically 11 significant P value, regardless of all of that, as 12 long as the number is more than one you will call 13 it a positive association? 14 A I would refer to that as a positive association, 15 yes. 16 Q Is that something that you have held to 17 methodologically your entire career as an 18 epidemiologist, or is this a new thing? 19 MS. PARFITT: Objection to form. 20 A This has been kind of discussed and emerging in 21 the epidemiologic literature over time. A lot of 22 that, I believe, has been driven by genetic 23 association studies, SNP studies. This was 24 actually what my dissertation work was in, was 25 looking at seven different SNPs in five different</p>
<p style="text-align: right;">Page 247</p> <p>1 be trusted, versus when a result may be due to 2 chance bias or confounding. 3 That is the purpose of statistical 4 significance, correct? 5 MS. PARFITT: Objection to form. 6 A I would say that the P value, again, is really 7 just to test a hypothesis. It usually does not 8 indicate bias or confounding. It's really more of 9 chance. 10 Q Yeah. 11 A However, it's an artificial number that we have 12 applied. A P value of less than .05 is considered 13 to be statistically significant. 14 There is no scientific statistical biological 15 reason that we have selected that as a cut point. 16 And for that reason, they are being used less in 17 medical literature and scientific literature. A 18 straight P value, it does not give you as much 19 information as a confidence interval would. 20 Q You don't have to agree with my terminology, 21 because I know you won't, but you are not just 22 putting aside the P value, you are putting aside 23 the confidence interval, also. Right? 24 I mean, these studies, these studies cross 25 one, several of the ones that you are calling</p>	<p style="text-align: right;">Page 249</p> <p>1 genes. That was back in 1999, 2000-ish. 2 That was when the field was really taking 3 off. And what they noticed, and "they" meaning 4 kind of like the collective scientific community, 5 is that these genetic effects could be, in terms 6 of the point estimate .05 might have been 7 categorized as a very low estimate. 8 But then when you look over the whole 9 population, you say, oh, forty percent of people 10 carry that particular variant that increases risk, 11 that might not be a statistically significant or 12 impressive, so to speak, odds ratio. But it is 13 very significant on a population level. 14 And that line of thinking, again, this is 15 when I was starting twenty years ago to come into 16 the field, I think that line of thinking has 17 really developed over time so that there is not 18 this reliance on it's statistically significant 19 so, therefore, it's important, versus it's not 20 statistically significant so, therefore, there is 21 no value. 22 Q So with your definition of positive association, 23 is it your contention that the cohorts and the 24 case controls on talc and ovarian cancer all 25 consistently demonstrate an association?</p>

<p>Page 250</p> <p>1 Or maybe with the exception of Sisters. 2 MS. PARFITT: Objection. Form. 3 You can answer. 4 A And the Sister Study I would remove not because of 5 the point estimate that they found. It's really 6 about the major issue with misclassification of 7 the exposure. 8 So I want to be clear that that would be the 9 reason that I would exclude Sisters. It would not 10 be because it did not go in the positive 11 direction. 12 It would be because they noticed, you know, a 13 flaw that they actually kind of tested and proved 14 was a flaw. But, yes, I think that there is 15 consistency between the majority of the case 16 control studies and the cohort studies. There is 17 a positive association. 18 Again, we are talking about a substance, we 19 are talking about talc here that has, like, no 20 medicinal benefit to women that we know of. And 21 yet it might increase risk of this disease that is 22 highly rapidly fatal. It has a terribly poor 23 prognosis and induces a lot of suffering. 24 Q All that is totally respected. The latter portion 25 of your comment there.</p>	<p>Page 252</p> <p>1 Q So you are aware that a lot of the literature out 2 there published to date on this accepts or states 3 that the cohorts are not detecting an association 4 and some of the case controls are. 5 That is published out there in the 6 literature. You have seen that characterization 7 of the cohort studies, correct? 8 MS. PARFITT: Objection. Form. 9 A I have seen that characterization. Yes, I have. 10 Q It's in a lot of the meta-analysis that you cite. 11 It's in all of the cohort studies that you cite. 12 We just looked at O'Brien where they said 13 they didn't detect an association. All of these 14 studies are using language to say, the cohorts, 15 are not detecting an association. 16 You would disagree with all of those pieces 17 of literature that characterize the cohorts that 18 way, is that correct? 19 MS. PARFITT: Objection to form. 20 A I don't disagree that those data are out there, or 21 those statements are out there. 22 I would disagree that we have four cohort 23 studies that have identified measures of 24 association that are lower than the vast majority 25 of case control studies.</p>
<p>Page 251</p> <p>1 That is a different issue, isn't it? Whether 2 or not ovarian cancer is a terrible disease and 3 all of the things that you just mentioned, 4 methodologically as an epidemiologist, right, when 5 you are trying to consider whether there is an 6 association, that, you know, that is a separate 7 issue from thinking about the public health 8 impact, isn't it? 9 MS. PARFITT: Objection to form. 10 A Yeah. Thinking about whether or not there is an 11 association versus the ultimate health impact, to 12 me at the end that, that is more in line with 13 trying to establish causality. 14 But back to, you know, the area of, you know, 15 does the meta odds ratio or relative risks or a 16 single study, is the association, is it nine 17 percent excess risk? Is it twelve percent? Is it 18 twenty-five percent? Is it forty percent? 19 You know, those numbers to me, again, in the 20 totality of all of the analysis, you know, say 21 it's essentially all in the same direction. Those 22 odds ratios are all in the same direction whether 23 it's the nine percent, whether it is the thirteen 24 percent, whether it's the twenty percent increase 25 in risk.</p>	<p>Page 253</p> <p>1 And that we as a field, you know, we have got 2 tens of thousands of cases that we have looked at 3 in these case control studies. We have a fraction 4 of that in those cohort studies. 5 As I mentioned at the beginning of today, 6 cohort studies are not well designed to answer a 7 question of a rare disease that takes years of 8 initiation. And, you know, that may be leading to 9 some of the differences that you see between those 10 point estimates. 11 Another concern of relying heavily on these 12 cohort studies is the fact that at entry into the 13 study, and I will use Women's Health Initiative as 14 an example, you have to be a post-menopausal 15 woman. 16 So any ovarian cancer that occurred 17 pre-menopausally, which is around seven or eight 18 percent of all ovarian cancers, were by definition 19 missed. And if you believe some of the other 20 literature that suggests that the effects of talc 21 are enhanced in a group of women who are either 22 pre-menopausal -- in the face or in the 23 interactions with estrogen -- so either on hormone 24 replacement therapy or pre-menopausal woman who 25 still have some at least some estrogen function.</p>

<p style="text-align: right;">Page 254</p> <p>1 You know, if those women were included in 2 these cohort studies, conceivably the point 3 estimates would be much more in alignment with 4 what we see in the case control studies. 5 The cohort studies are not the best study 6 designed to answer this question. 7 Q And the point estimate you have put in your report 8 in several places is 1.25, correct? 9 A Yes. 10 Q Is that the number that you land on as an expert 11 that you think the association from the totality 12 of the evidence is a 1.25, correct? 13 MS. PARFITT: Objection. Form. 14 A Yeah. If I had to give a single number, I would 15 say, yes, about 1.25 based on the available 16 evidence. 17 Q I'm just reading from your report. 18 A Yes. That does not consider, you know, whether we 19 have an open or closed tract. If it was in a 20 patent tract, it might be a little higher. 21 Q Okay. With respect to your testimony that the 22 cohorts show a positive association -- 23 A Yes. 24 Q -- you have in prior literature previously 25 commented on the cohort studies, correct?</p>	<p style="text-align: right;">Page 256</p> <p>1 Q At the very bottom you say, "The Women's Health 2 Initiative, WHI, did not detect an association 3 with genital talc use and EOC." 4 Do you see that language? 5 A I do. 6 Q Do you agree that that statement is true today? 7 A I believe with -- yes. I would say based on -- so 8 this was based on 2016, but really probably more 9 like 2015 that, yes, based on all of the other 10 information I have from eight years later, I no 11 longer agreement with this statement. 12 Q So today you are changing, or you would change how 13 you would write this sentence? 14 A Right. I would say did not detect a statistically 15 significant. 16 Q Is that because of the result of O'Brien or 17 because of these other lines of evidence that you 18 have considered? 19 A It's actually both. 20 Q You said in 2016 in a published paper before you 21 were a retained expert in the litigation that the 22 WHI did not detect an association with genital 23 talc use and EOC. 24 Those were your words as a co-author, 25 correct?</p>
<p style="text-align: right;">Page 255</p> <p>1 MS. PARFITT: Objection. Form. 2 I'm not sure what cohort -- 3 A And I'm not sure prior literature. 4 Q Okay. Well, today your testimony in this room is 5 that the cohorts show a positive association, 6 correct? That is your testimony. You are talking 7 about the WHI and the NHS, correct? 8 A That is of my intensive read of everything that is 9 available to date including, you know, some of the 10 comments to the editor. Yes. 11 Q Which we will get to hopefully. So I will mark as 12 Exhibit Number 21 your Schildkraut study. 13 (EXHIBIT NUMBER 21 WAS MARKED FOR 14 IDENTIFICATION.) 15 A Yes. 16 Q This is the study in which you were a co-author 17 that looks at body power use and ovarian cancer? 18 A Yes. 19 Q Again, this is a paper you co-authored with 20 Moorman, Schildkraut and many others, correct? 21 A Yes. 22 Q Look at the bottom of the first page for me. 23 A Okay. 24 Q There you are summarizing prior studies. 25 A Yes.</p>	<p style="text-align: right;">Page 257</p> <p>1 A Those were the findings, yes. 2 Q You go on to say that, "Neither prospective study 3 found evidence of a dose-response relationship." 4 Do you see that language? 5 A Yes. 6 Q Will you agree that that is still true today? 7 A Yes, I would. 8 Q So you do agree that the prospective studies do 9 not find evidence of a dose-response relationship, 10 correct? 11 A At the time of this publication I would say that 12 is correct. 13 Q Do you agree -- 14 A But that was really only two studies. 15 Q Okay. Do you agree to this day that WHI and NHS, 16 which were published before this -- 17 A Yes. 18 Q -- that those studies do not find evidence of a 19 dose-response relationship? 20 A I'm going to actually look at my meta-analysis. 21 I'm sorry. My cohort analysis table. 22 Because what occurred between the time that 23 these initial studies were published and the 24 findings that were summarized in O'Brien is they 25 add cases. As the cohort ages and develops more</p>

<p style="text-align: right;">Page 258</p> <p>1 cases are added. 2 So, again, I am now looking at the Table 4. 3 I'm really looking at WHI number of cases based on 4 the 2014 which is 429 cases. 5 Then if we can go back to the O'Brien 6 analysis, Exhibit 20. Yeah. The Women's Health 7 Initiative study here, it went from, you know, 8 what was originally published in 2014, so prior to 9 the writing of the Schildkraut paper, they had 429 10 cases. Now they have got 649 cases. So not quite 11 doubling. No. Not quite a doubling. But, you 12 know, a large additional amount of data was 13 included in the O'Brien papers. 14 Q Again, my question that we are on right now is 15 whether you still agree that neither NHS nor WHI 16 found evidence of a dose response relationship. 17 Do you agree with the statement that you made 18 in 2016, do you agree with that today? 19 MS. PARFITT: Objection. Form. Asked and 20 answered. 21 A Yes. 22 Q But you do not agree with the prior sentence that 23 you wrote in 2016. 24 You no longer agree that the WHI did not 25 detect an association. You would amend that</p>	<p style="text-align: right;">Page 260</p> <p>1 introduction to the article. 2 Q To be honest, I don't know the precise chronology. 3 Do you recall seeing this? 4 A I believe so. 5 Q Okay. 6 A I thought -- I can tell by the dates on it. This 7 is like the introductory commentary about the 8 article. 9 Q Okay. 10 A Yes. 11 Q I want to ask you about a specific passage. Turn 12 over to the second page. 13 On Page 30 there is a paragraph there that 14 starts with, "Given this putative mechanism of 15 exposure..." 16 Do you see that? 17 A Yes. They are speaking about inflammation. 18 Q Okay. And they go on to talk about a 19 classification issue. You can read that 20 paragraph. That is between patent and not patent. 21 Read that paragraph. Then I want to ask you 22 a question. 23 A Got it. I'm through it. 24 Q So in that paragraph one of the issues that they 25 are discussing is the classification of patent</p>
<p style="text-align: right;">Page 259</p> <p>1 today -- 2 A Correct. 3 Q -- in the context of litigation, correct? 4 MS. PARFITT: Objection to the form. 5 A Correct. I would amend that. 6 MS. PARFITT: We have gone about an hour. 7 Can we take a little break? 8 (OFF RECORD AT 4:03 P.M.) 9 (AT THIS TIME A SHORT RECESS WAS HELD OFF 10 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS 11 WERE HAD:) 12 (ON RECORD AT 4:19 P.M.) 13 BY MR. JAMES: 14 Q With respect to the O'Brien article, did you read 15 the accompanying letter written by Gossett? 16 A Let me see. 17 Q I did not see Gossett listed, in full disclosure. 18 A If I did not -- 19 Q Let me mark it and hand it to you. 20 A Okay. 21 (EXHIBIT NUMBER 22 WAS MARKED FOR 22 IDENTIFICATION.) 23 Q Does that letter look familiar to you? 24 A Yes, it does. I think this was published at the 25 same time, was it not? Kind of like an</p>	<p style="text-align: right;">Page 261</p> <p>1 versus non-patent, correct? 2 A Yes. 3 Q Do you agree that the stratification of women into 4 patent and non-patent does not clearly group women 5 into exposed and non-exposed categories for the 6 reasons that they stated? 7 MS. PARFITT: Objection. 8 A I would agree if you are just looking at kind of 9 gross measure of exposure. But it does not, there 10 is, like, a curtailing of exposure that could 11 occur in women who have had, you know, a 12 hysterectomy or oophorectomy or tubal ligation. 13 So it could be a curtailing of that exposure. 14 It gives you some additional information. 15 Q Okay. But you are agreeing that there is some 16 merit to what they are saying about the 17 classification issue? 18 MS. PARFITT: Objection. Misstates 19 testimony. 20 A I'm saying this provides additional information. 21 What is described here is what we would call -- it 22 is a potential effect modifier. When you divide 23 one group into two different groups to see if the 24 association differs between those two groups. 25 Here they argue because it's not</p>

<p style="text-align: right;">Page 262</p> <p>1 statistically different, the HR in the patent 2 group of 1.13 and the non-patent group of .99, 3 they are arguing that it's not a statistically 4 significant difference. So, therefore, it is not, 5 in their mind, important.</p> <p>6 Q Okay. I guess you are talking about the 7 heterogeneity test they ran between the two 8 subgroups?</p> <p>9 A Yes.</p> <p>10 Q In O'Brien, and Gossett re-emphasizes, there was 11 not a statistically significant difference between 12 the two subgroups, correct?</p> <p>13 A Not statistically significant, correct.</p> <p>14 Q The conclusions they draw from that finding are 15 that because of that, you actually really can't 16 say that there was a difference between the 17 association between patent and non-patent? 18 They are hinging on statistical significance?</p> <p>19 MR. TISI: Who is they? Gossett or 20 O'Brien?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 Q Gossett.</p> <p>23 A Yes. That is what Gossett states.</p> <p>24 Q O'Brien notes that as well. They note that they 25 ran the heterogeneity test, correct?</p>	<p style="text-align: right;">Page 264</p> <p>1 Q And another point they make is that actually 2 trying to bucketize these two groups of study 3 participants in the patent and non-patent does not 4 really classify them into exposed versus 5 non-exposed.</p> <p>6 Did you see that point they were making as 7 well?</p> <p>8 MS. PARFITT: Objection. You are still 9 talking Gossett, right?</p> <p>10 Q Sure. Yes. For the Gossett article, one of the 11 points they are making is that the stratification 12 does not clearly group the women into exposed and 13 unexposed, correct?</p> <p>14 That is what they are saying?</p> <p>15 A Correct. Because women who had been using, for 16 example, during their adolescent years who had a 17 tubal ligation in their thirties, they were only 18 exposed -- it curtails the exposure. They are 19 potentially exposed up until that time.</p> <p>20 Q Do you think there was some merit to that point, 21 that the stratification does not actually properly 22 get the case study participants into exposed and 23 unexposed?</p> <p>24 Do you think there is some merit to that 25 point?</p>
<p style="text-align: right;">Page 263</p> <p>1 A Correct. But the heterogeneity test, again, is a 2 P value. It's based on the simple kind of like a 3 yes or no, versus looking at the hazard ratios. 4 One does still, you know, suggest and, in 5 fact, if you are going to look at one P value or 6 argue statistical significance in one area, it is 7 now statistically significant at 1.01 to 1.26 8 confidence interval.</p> <p>9 Q Okay. We have talked about your position on 10 statistical significance already today, correct?</p> <p>11 A Correct.</p> <p>12 Q Does that position apply in your mind to this 13 issue as well, the statistical significance of 14 heterogeneity?</p> <p>15 MS. PARFITT: Between patent and 16 non-patent?</p> <p>17 A Between these two groups?</p> <p>18 Q Yes.</p> <p>19 A Yes. My opinion is that, you know, once you start 20 stratifying data in any sort of way when you 21 already have a limited number of, you know, 22 subjects, you are just absolutely losing the power 23 to detect differences between the groups.</p> <p>24 That is what the test for heterogeneity is, 25 is there a difference between the groups or not.</p>	<p style="text-align: right;">Page 265</p> <p>1 MS. PARFITT: Objection.</p> <p>2 A I think there is merit to that point. I think it 3 adds some information about the length of 4 exposure.</p> <p>5 Q Okay. Do you have any concerns with the power of 6 the cohort studies to detect the level of 7 association that you ascribe, which is the 1.25?</p> <p>8 A I feel on their own they would be underpowered to 9 detect that association.</p> <p>10 As a group, despite the fact that they ask 11 questions somewhat differently, they have had to 12 harmonize data that are perhaps not perfectly able 13 to be harmonized because it's not the exact same 14 question being asked for the exact same timeframe 15 for all these studies.</p> <p>16 So it's a less than perfect harmonization. I 17 do think that it is potentially still 18 underpowered.</p> <p>19 Q And "it" you are referring even with O'Brien?</p> <p>20 A Yes. Even summarized together.</p> <p>21 Q Let's look at your report.</p> <p>22 A Uh-huh.</p> <p>23 Q Let's look at Page 20. At the very bottom of 24 Page 20 you talk about these various metas.</p> <p>25 A Yes.</p>

<p style="text-align: right;">Page 266</p> <p>1 Q You are talking about Berge. At the very bottom, 2 the second to bottom sentence you say, and you are 3 quoting here, "Thus, low power of cohort studies 4 cannot be invoked as explanation of the 5 heterogeneity of results."</p> <p>6 Do you see that sentence that I read? That 7 is from Berge, correct?</p> <p>8 A I'm missing where you are.</p> <p>9 Q No worries. Three from the bottom.</p> <p>10 A Okay. So I'm seeing, "It should be noted that the 11 cohort --"</p> <p>12 Q Yes. Just read to yourself.</p> <p>13 A Okay.</p> <p>14 Q Then carry on to finish that hanging sentence.</p> <p>15 A Yes. So they are noting that it was just -- they 16 note the 429 in this WHI study. "So while the 17 statement isn't completely correct, the point is 18 the same. Power also depends on the variation of 19 the prevalence of the exposure between cases and 20 controls, but it is not described."</p> <p>21 I just felt like that is not necessarily a 22 complete power analysis. It does not give me 23 enough information.</p> <p>24 Q Okay. I read that sentence to indicate that you 25 sort of agreed with the proposition in Berge that</p>	<p style="text-align: right;">Page 268</p> <p>1 underpowered to detect the magnitude of 2 association that you are claiming in your report, 3 which is the 1.25?</p> <p>4 A I would say that I do not have enough detail, nor 5 have I performed a post-hoc power analysis because 6 that is also something that, generally speaking, 7 we try to power studies upfront versus 8 retrospectively, to really, to make that statement 9 clearly.</p> <p>10 I go back to compared to a very well-designed 11 case control study, and there are a number of 12 them, that these cohorts are still underpowered to 13 detect associations of that magnitude.</p> <p>14 And, further, they have got some issues with 15 either classification or selection bias at the 16 time of study entry that makes them kind of have 17 different concerns than case control studies, but 18 there are still concerns with regards to the 19 methodology and the ultimate findings.</p> <p>20 There are strengths and weaknesses of both 21 types. Cohort studies are perhaps not as well 22 suited as the case control.</p> <p>23 And because the case control has kind of been 24 the standard for decades for this research 25 question, there is just a lot more data there and</p>
<p style="text-align: right;">Page 267</p> <p>1 low power was not really a problem.</p> <p>2 Did I misread that?</p> <p>3 A Yes.</p> <p>4 MS. PARFITT: Objection. Form.</p> <p>5 Q That is fine. That is all I needed.</p> <p>6 A Okay.</p> <p>7 Q Your contention today, you believe that even with 8 O'Brien there is still a power problem, is that 9 correct?</p> <p>10 A For the --</p> <p>11 MS. PARFITT: Objection to the form.</p> <p>12 It's a bit vague, Scott, when you read the 13 record.</p> <p>14 Do you want to try that one again?</p> <p>15 Q Sure. Even with the O'Brien study. The data --</p> <p>16 A The four cohort study analysis in the 2020 paper?</p> <p>17 Q Yes. The O'Brien 2020 paper which collects more 18 data on the cohorts, correct?</p> <p>19 A Yes. Correct.</p> <p>20 Q So that is the most recent analysis we have of the 21 cohort data, correct?</p> <p>22 A Yes.</p> <p>23 Q And O'Brien 2020?</p> <p>24 A Yes.</p> <p>25 Q Okay. Do you believe that O'Brien 2020 was</p>	<p style="text-align: right;">Page 269</p> <p>1 a lot more detailed data there.</p> <p>2 Q Okay. In your table on Page 22 of your report --</p> <p>3 A Yes.</p> <p>4 Q -- you include a summary table of the 5 meta-analyses and Terry and O'Brien pooled 6 analyses, correct?</p> <p>7 A Yes.</p> <p>8 Q For the O'Brien article you have listed only the 9 association for patency, correct?</p> <p>10 A Yes.</p> <p>11 Q You did not do that for any of the other studies, 12 correct?</p> <p>13 A Correct. I highlighted that one because the 14 patency issue to me was the standout point in 15 O'Brien.</p> <p>16 So that is really just to remind myself that 17 this is, this is something that came up. In 18 particular, it came up in the response to the 19 reviewer.</p> <p>20 Just to be clear, this first editorial is 21 published at the time of the O'Brien paper as kind 22 of a highlight. These are usually invited reviews 23 by the Journal. That is the Gossett paper, 24 Exhibit 22.</p> <p>25 Whereas, the commentary that came up after</p>

<p style="text-align: right;">Page 270</p> <p>1 O'Brien and then the invited commentary from a 2 year or so later, really reverses her overall 3 statement that there was no association seen. And 4 that was why I listed that to highlight that one.</p> <p>5 Q So your contention is that in this Table 3 you 6 have listed O'Brien 2020 patent numbers only.</p> <p>7 A Uh-huh.</p> <p>8 Q That is, in part, because you believe O'Brien has 9 reversed her conclusions from her 2020 paper, is 10 that correct?</p> <p>11 A It was just to draw my attention to it, similar to 12 Davis above that. The focus of the Davis paper 13 was to see if there were any differences between 14 African-American and White women with respect to 15 risk. You know, similar to the Phung paper where 16 I list the endometriosis and no endometriosis.</p> <p>17 It's really just to give myself and those 18 reading, you know, anything notable about the 19 study. And that was with the O'Brien original 20 study from 2020, the original analysis, that was 21 what stood out to me there.</p> <p>22 Q Is your position that from O'Brien 2020, the only 23 finding left standing after this so-called 24 reversal is the patency finding?</p> <p>25 MS. PARFITT: Objection to form.</p>	<p style="text-align: right;">Page 272</p> <p>1 expert for the plaintiffs?</p> <p>2 A No, I know that Dr. Cramer published the first 3 study in 1992. This has pretty much been his 4 life's work. I don't know if he was ever 5 retained, I don't know for any of them if they 6 were retained by the plaintiffs and what date, as 7 well as by the defense and what date.</p> <p>8 Can you go back and forth?</p> <p>9 Q I'm trying to move us along. The Cramer 2016 10 paper that you cited, did you see a disclosure in 11 that paper?</p> <p>12 Do you recall that?</p> <p>13 A I don't recall.</p> <p>14 Q Regardless, with respect to the letters to the 15 editor and then you said Dr. O'Brien wrote a 16 response, correct?</p> <p>17 A Correct.</p> <p>18 Q If you look at the bottom of Page 19 of your 19 report --</p> <p>20 A Yes.</p> <p>21 Q -- you have underlined and are referring to her 22 response, correct?</p> <p>23 A Her response, yes.</p> <p>24 Q You say, "This reverses the conclusion of the 25 original manuscript that stated 'there was not a</p>
<p style="text-align: right;">Page 271</p> <p>1 A No. No, not at all.</p> <p>2 Q The letters to the editor that you are identifying 3 are from Cramer, Harlow, and Roth, correct?</p> <p>4 A Yes. Those were the ones, yes.</p> <p>5 Q We talked this morning, those are all retained 6 experts for the plaintiffs, correct?</p> <p>7 A I believe so.</p> <p>8 Q On Page 19 when you say -- we will use this exact 9 language. Page 19 of your report --</p> <p>10 A At what point in time? Can we revisit that?</p> <p>11 At what point in time were they --</p> <p>12 Q Was that an objection counsel made or was that a 13 point?</p> <p>14 MS. PARFITT: I objected to the question.</p> <p>15 I think she was still talking. I don't know. I 16 turned to Chris.</p> <p>17 MR. TISI: She was talking.</p> <p>18 MS. PARFITT: I thought you were still in 19 your explanation.</p> <p>20 Q Do you know how long Cramer --</p> <p>21 MS. PARFITT: Can she finish?</p> <p>22 A I was asking at the time, you know, were they --</p> <p>23 Q Do you know?</p> <p>24 A I don't.</p> <p>25 Q Do you know how long Dr. Cramer has been a paid</p>	<p style="text-align: right;">Page 273</p> <p>1 statistically significant association between use 2 of powder in the genital area and ovarian 3 cancer'."</p> <p>4 That is the language from your report, is 5 that correct?</p> <p>6 A Yes, that is.</p> <p>7 Q Are you contending that the entire manuscript is 8 reversed?</p> <p>9 Are you contending that the only thing left 10 standing is the patency finding?</p> <p>11 What was reversed in your mind?</p> <p>12 A The conclusion that is stated there in the 13 manuscript, or underlined there in the manuscript, 14 we can go back to the original manuscript if 15 necessary, it states there was not a statistically 16 significant association between the use of powder 17 in the genital area and ovarian cancer.</p> <p>18 If we are going to be picky about 19 statistically significant, there was a 20 statistically significant association amongst the 21 women with the patent reproductive tract.</p> <p>22 Her other findings, I don't debate the other 23 findings in terms of, you know, what she stated 24 about those.</p> <p>25 But, again, you know, there can be a positive</p>

<p style="text-align: right;">Page 274</p> <p>1 association that is not statistically significant 2 and it can still be meaningful.</p> <p>3 Q Has a retraction to the O'Brien 2020 article been 4 published?</p> <p>5 A I think that the review that she wrote a year 6 later, it is not an official retraction of this 7 2020 paper, but I believe it, if not completely 8 reverses her findings, I think it restates them in 9 a manner that states that there is a positive 10 association between talc use and ovarian cancer.</p> <p>11 Q Has JAMA issued any sort of statement or 12 retraction?</p> <p>13 A No. But it would be unusual for a journal to do 14 so unless there were issues in terms of, like, if 15 the data were misrepresented or out of order, 16 something along those lines. Or if they found 17 there was any kind of fabrication of data.</p> <p>18 And I'm not suggesting that whatsoever.</p> <p>19 Q Have you talked with any of the authors of the 20 O'Brien paper?</p> <p>21 A No.</p> <p>22 Q With all due respect, to say that something was 23 reversed via a letter to the editor is a pretty 24 remarkable claim, don't you think?</p> <p>25 MS. PARFITT: Objection.</p>	<p style="text-align: right;">Page 276</p> <p>1 came up in the Cramer discussion, as well as the 2 earlier discussion, the second letter that I 3 referred to from Harlow and Rothman.</p> <p>4 Q Do you agree with O'Brien's response where she 5 still highlights that recall bias is still present 6 in the retrospective studies?</p> <p>7 Do you agree with that portion of the 8 response, also?</p> <p>9 A I would have to go and see exactly what she had to 10 say.</p> <p>11 But globally do I agree with the statement 12 that recall bias may be present in some case 13 control studies depending on the exposure, yes.</p> <p>14 Q Did all of the authors on the O'Brien 2020 paper 15 sign on to this letter response?</p> <p>16 A I don't have that knowledge. We can look and see.</p> <p>17 MS. PARFITT: Scott, are you talking about 18 the O'Brien reply? I have a copy. Let me show it 19 to her.</p> <p>20 MR. JAMES: Okay. Go for it.</p> <p>21 MS. PARFITT: Mine is highlighted.</p> <p>22 MR. JAMES: No worries. I will just mark 23 it as well.</p> <p>24 MS. PARFITT: Oh, no.</p> <p>25 A I should have a copy. Let me see what number it</p>
<p style="text-align: right;">Page 275</p> <p>1 Counsel, is that an argument or a question?</p> <p>2 MR. JAMES: It's clearly a question.</p> <p>3 Q I mean, it seems remarkable to me.</p> <p>4 Does it seem remarkable to you to claim that 5 an article or a finding has been reversed through 6 a letter to the editor response?</p> <p>7 MS. PARFITT: I will object. That is what 8 she put in the report.</p> <p>9 The question is whether it's remarkable to 10 her?</p> <p>11 MR. JAMES: Yes, that is what I am asking.</p> <p>12 Q Professionally is it remarkable for you to make 13 that claim?</p> <p>14 MS. PARFITT: Objection to the question.</p> <p>15 A I don't think it's remarkable for me to make the 16 claim. I think it's a statement of fact. She 17 reversed the conclusion in the original manuscript 18 that stated there was not a statistically 19 significant association between use of powder in 20 the genital area and ovarian cancer.</p> <p>21 You know, there was a statistically 22 significant association that was found. And, you 23 know, what was most striking to me about all of 24 this was really just how readily the original 25 authors of O'Brien agreed with the points that</p>	<p style="text-align: right;">Page 277</p> <p>1 is. 76.</p> <p>2 Q Here, I will just hand you a copy.</p> <p>3 A I have it.</p> <p>4 Q Exhibit 23 is the O'Brien response letter. 5 (EXHIBIT NUMBER 23 WAS MARKED FOR 6 IDENTIFICATION.)</p> <p>7 Q Okay.</p> <p>8 A So in reply --</p> <p>9 Q All I'm asking you about is the second paragraph 10 where she says, "Conversely, empirical evidence 11 supports that recall bias is present in 12 retrospective studies."</p> <p>13 Do you see that sentence?</p> <p>14 A Yes.</p> <p>15 Q Do you agree with that sentence?</p> <p>16 A I want to see what empirical evidence she cites.</p> <p>17 It's the Schildkraut paper. Yes. I have already 18 stated that there is evidence of recall bias.</p> <p>19 The other paper there, the Trabert was 20 actually, kind of like this Gossett paper, was an 21 editorial prior to or it was published at the same 22 time. That is what the Trabert paper was to 23 Schildkraut. So it is really using the same piece 24 of evidence there, that case control study.</p> <p>25 So that is one study amongst almost three</p>

<p style="text-align: right;">Page 278</p> <p>1 dozen studies that support recall bias, that show 2 evidence that there is potential recall bias. 3 The recall bias we believe as an author on 4 that study was introduced because of this talc 5 litigation. All of those other prior studies, 6 they asked those questions years, if not decades, 7 before in different countries even and we saw the 8 same results. 9 So the empirical evidence that she states is 10 based on exactly one study. 11 Q So you think that the medical and scientific 12 community believes that the only source of recall 13 bias in the talc ovarian cancer studies is the 14 onset of litigation in 2014? 15 MS. PARFITT: Objection. Misstates her 16 testimony. 17 A Yeah. No, I never stated that. I stated that the 18 empirical evidence that she cites here to 19 support -- this empirical evidence supports that 20 recall bias is present in retrospective studies, 21 she just really cites one source, which is that 22 Schildkraut paper. That is it. 23 Q But she is just writing a response letter, 24 correct? 25 A Well, sure.</p>	<p style="text-align: right;">Page 280</p> <p>1 at it right now? 2 A Yes. 3 Q You also stated in your report that you give more 4 weight to invited reviews, something along those 5 lines, is that correct? 6 MS. PARFITT: Objection to the question. 7 You can answer. 8 A Yeah. I'm not sure I said I give more weight to 9 invited reviews. I do think I give less weight to 10 just investigator initiated general reviews. 11 Q Okay. For the Wentzensen and O'Brien 2021 12 article, are you aware that they stated in that 13 article that it is difficult to conclude that the 14 observed associations are causal? 15 Do you recall that language? 16 MS. PARFITT: Can you tell us, are you at 17 a specific place? 18 Q I didn't see that highlighted in your report. I 19 was wondering if you noticed that observation? 20 MS. PARFITT: Objection to form. 21 A The observation I see related to that in the 22 abstract is kind of buried in the middle that says 23 the causal factors underlying this association are 24 not clear. 25 Q Okay. So I've just handed you what I have marked</p>
<p style="text-align: right;">Page 279</p> <p>1 Q Would you have liked her to have done an expose 2 on recall bias in the talc ovarian cancer studies? 3 MS. PARFITT: You asked her two questions. 4 Do you want her to answer both? 5 You have two questions out there, Scott. 6 A Now I have forgotten the two questions. 7 Q Okay. Let's just move on. 8 A Okay. The original question, as to did everyone 9 sign off, O'Brien, Sandler, Wentzensen on the 10 original paper was -- it was, yes, three out of 11 four. Actually, I don't know who this -- no. No. 12 Not the 2000. Not this one. The 2020. No. 13 So who signed off on it? It was the senior, 14 or the senior author, Wentzensen. Then Dale 15 Sandler and Dr. O'Brien. So the first and the two 16 most senior authors signed off. 17 So, no, it was not signed off on by 18 everybody. Thank you for that. 19 Q A few moments ago you referred, I believe, to the 20 2021 review article by Wentzensen and O'Brien, 21 correct? 22 A Yes. 23 Q Okay. 24 A I'm trying to get to it. 25 Q You discuss that in your report. You are looking</p>	<p style="text-align: right;">Page 281</p> <p>1 as Exhibit Number 24. 2 (EXHIBIT NUMBER 24 WAS MARKED FOR 3 IDENTIFICATION.) 4 A Yes. 5 Q Let's look at Page 9. In this article that 6 postdates the O'Brien article from 2020, and it 7 postdates the letter to the editor response. 8 Dr. O'Brien published this article, correct? 9 A Yes. 10 Q That was a clunky question, but this came after? 11 A Yes. 12 Q We can see at the top of Page 9 in this review 13 Dr. O'Brien says that, "Independent of the 14 underlying cause, the association between powder 15 use and ovarian cancer is weak." 16 Do you see that? 17 A I do. 18 Q Would you agree with her that the association is 19 weak? 20 A No, I would not characterize an association as 21 weak. I might characterize, you know, other 22 factors. But an association I would characterize 23 with a point estimate. 24 Q You would never -- 25 A A number. I would not try to assign some sort of</p>

<p style="text-align: right;">Page 282</p> <p>1 scale that if it was between X and Y it's weak and 2 if its between Y and Z it's moderate and so forth. 3 Q If I hear you correctly you would not, as an 4 epidemiologist, refer to an association as weak or 5 modest or strong, is that correct? 6 Did I understand you correctly? 7 A Yes. In my work today and how I write now I would 8 just present the data. 9 Q Do you recognize that an association of 3.0 is 10 stronger than an association of 1.5? 11 A I would say it's larger at this point. I don't 12 know if I would use the terminology stronger any 13 more. 14 Q If you look down below in that same paragraph 15 below the 32 note, here is the language I was 16 referring to. 17 A Okay. 18 Q She says, "Given the inability to attribute a 19 clear causal factor to the observed associations, 20 the lack of a good experimental model, the lack of 21 a specific biomarker for powder-related 22 carcinogens, and the inability to rule out 23 confounding by indication, it's difficult to 24 conclude that the observed associations are 25 causal."</p>	<p style="text-align: right;">Page 284</p> <p>1 When they talk about things like the lack of 2 a good experimental model, the lack of a specific 3 biomarker for powder-related carcinogenesis, and 4 then the lack of -- where am I -- and the 5 inability to rule out confounding by indication, 6 there's a lot of other associations in the world 7 of cancer more broadly that we don't have those 8 sorts of things for but that, again, we as either 9 the scientific community or as, you know, the 10 larger community as a whole still consider to be 11 even without this clear causal factor that they 12 are looking at or these clear biomarkers, that 13 point, you know, with the hundred percent 14 certainty that this is it. 15 We make policy decisions every day that are 16 based on things with a lot less evidence than what 17 they, the standard that they are holding to 18 causality here. 19 A good example of that comes, again, from 20 my -- 21 Q Dr. Cote, my time is really limited. This is not 22 really responsive to my question. 23 MS. PARFITT: I believe it is. Let her 24 finish. She will make it efficient. 25 MR. JAMES: Counsel has an opportunity --</p>
<p style="text-align: right;">Page 283</p> <p>1 Did I read that correctly? 2 A You read that correctly. 3 Q Despite our back and forth on what the letter 4 response meant, at least as of 2021 Dr. O'Brien is 5 still expressing that it's difficult to conclude 6 that the association is causal, is that fair? 7 MS. PARFITT: Objection. 8 A I would say based on what she has written here, 9 that is true. 10 Q I appreciate you do not agree with her. But at 11 least in 2021 we can see that she has put this pen 12 to paper, correct? 13 MS. PARFITT: Objection to form. There 14 are two authors on here. 15 A Yes. There are two authors. But I would also say 16 that I feel like this is a really high bar that 17 they are setting here. 18 So when they say the inability to attribute a 19 clear causal factor to the observed associations, 20 a clear causal factor does not make a lot of sense 21 to me. 22 I think what they are trying to say is that 23 talc is not a clear causal factor. So I'm 24 confused about that little portion of the 25 sentence.</p>	<p style="text-align: right;">Page 285</p> <p>1 MS. PARFITT: I'm sure she will bring it 2 to a close. Let her at least finish that 3 thought. 4 A I will bring it to a close right now in saying 5 lung cancer, for example, we make policies about 6 pollution and we make policies about radon where 7 those policies have been in place before or in 8 lieu of not having a specific signature for you 9 are exposed to radon or that that air pollution is 10 driving this association. 11 Those are associations that we see that are 12 in about the same magnitude of the associations we 13 are seeing here with ovarian cancer. So they have 14 a really high bar here of causality in my expert 15 opinion. 16 Q Are you aware of other associations in the same 17 range of a 1.25 that have been deemed to be not 18 causal? 19 A With respect to ovarian cancer? 20 Q Or any cancer? 21 A I have not done a literature review looking at 22 causality. Causality is what takes hundreds of 23 hours of review. 24 Q In your report you cite to examples of other 25 associations in the same magnitude as talc that</p>

<p style="text-align: right;">Page 286</p> <p>1 you deem to be analogous or relevant in some way. 2 Specifically you cite to colorectal cancer, 3 right? 4 A As one. Is this the executive summary? I'm sorry 5 to interrupt. 6 Q My question is more in general, are you aware of 7 any associations in the 1.25 range that are not 8 causal just across the world of cancer 9 epidemiology? 10 A Sure. There could be those associations that are 11 not causal. It could be an association that is 12 simply being driven by a confounding. 13 Q You didn't cite any examples of that in your 14 report, correct? 15 A No. Because I was, you know, trying to establish 16 whether or not there was causality. I didn't go 17 through and do a causal association analysis 18 looking at all of the different factors associated 19 with Bradford Hill for, you know, I would have 20 never completed this in that timeframe. This 21 would have been another several hundred hours of 22 work. 23 Q With respect to meta-analyses on Page 22 of your 24 report, please. 25 A Okay. I am there.</p>	<p style="text-align: right;">Page 288</p> <p>1 meta-analyses that show consistency, right, to say 2 that all of those meta-analyses are consistent, 3 one also cannot disregard the fact that the 4 consistency is, in part, at least driven by the 5 fact that they are all crunching the same numbers, 6 correct? 7 MS. PARFITT: Objection to form. 8 A I would say overall that that is a correct 9 statement. In the most recent meta-analyses, 10 again, they have been trying to examine the data 11 in different ways that provide more insight about 12 the exposure or about other potential factors 13 associated. 14 For example, the Phung study with 15 endometriosis. The Woolen study looking at kind 16 of the higher ends of exposure in the studies. 17 They are trying to look at different ways to 18 classify the exposures that adds something novel. 19 Q The meta-analyses that consider the same data 20 build on one another, correct? 21 A That is correct. 22 Q You are making that point in your report? 23 A Yes. 24 Q Meta-analyses also do not correct for underlying 25 problems with the data?</p>
<p style="text-align: right;">Page 287</p> <p>1 Q You say below the table that the meta-analyses 2 were consistent in reporting a positive 3 association between ever never talc use, correct? 4 That is in the first sentence. 5 A Yes. 6 Q You say, "This is not entirely surprising, as each 7 newer meta-analysis contains the studies examined 8 in the earlier meta-analyses, in addition to more 9 recent publications." Correct? 10 A Yes. 11 Q With respect to meta-analyses, as time goes by 12 they are continuing to count the same data and 13 then adding what is new? 14 A Correct. 15 Q And then the point you are making here that the 16 results are consistent is not entirely surprising, 17 it's because the meta-analyses are using a lot of 18 the same data, correct? 19 MS. PARFITT: Objection. Form. 20 A Correct. I'm definitely pointing out here that 21 these data from these earlier studies are being 22 reused, which is absolutely within the standard 23 accepted methodology. You would be questioned if 24 you were excluding them. 25 Q Of course. But to say that the number of</p>	<p style="text-align: right;">Page 289</p> <p>1 MS. PARFITT: Objection to form. 2 Q I will be more precise. Meta-analyses do not 3 correct for recall bias that is embedded in the 4 data, correct? 5 A Actually that is not an entirely correct 6 statement. Most meta-analyses use adjusted 7 estimates from each of the studies. Those 8 estimates are from adjusted models that reduce the 9 effects of confounding. 10 That is one of the goals of adjusting for 11 different variables and models. 12 Q Did you say confounding? 13 A Yes. 14 Q What about recall bias? If the case control 15 studies here, and I appreciate your opinion may be 16 different, but if the case control studies on talc 17 and ovarian cancer have recall bias and if they 18 have significant recall bias, that is not erased 19 by putting these all into the meta-analysis 20 machine, is it? 21 MS. PARFITT: Objection to form. 22 Q The recall bias is still there? 23 A I think all of the studies that are included, and 24 certainly some of these meta-analyses try to 25 address this by giving some grading system to each</p>

<p>Page 290</p> <p>1 of the studies.</p> <p>2 How we manage recall bias, one of the ways of 3 managing recall bias, again, if it exists, and 4 I'm, you know, my statement is that I do not 5 consider recall bias to be a significant issue in 6 these case control studies other than what was 7 shown in Schildkraut.</p> <p>8 We do it through the methodology of study 9 collection. We do it through very standardized 10 questionnaires. We do it through the training of 11 staff. We do it through how we design the 12 questionnaires to ask a large number of questions.</p> <p>13 So those are all methods that have shown that 14 recall bias can be reduced, if not eliminated, 15 using some of these techniques. And so it's the 16 quality of the studies that are included.</p> <p>17 One of the advantages of case control studies 18 is that you can do a very well designed case 19 control study that asks a lot more detailed 20 questions about exposures.</p> <p>21 Q Did you testify that the meta-analyses have 22 eliminated the recall bias in the case control 23 studies?</p> <p>24 A I'm not saying that they have eliminated it 25 through meta-analysis. I'm saying that the design</p>	<p>Page 292</p> <p>1 two different institutions.</p> <p>2 And, you know, some of the things that are 3 gold standard in terms of how you interview or 4 extract information from people across the board 5 are things that I look for in all of these 6 studies. They were things that I talked about 7 about the structured questionnaires, about 8 training of staff.</p> <p>9 I can say for Schildkraut, because I was 10 involved in that process, we absolutely did that 11 and it was never a one time thing. We went back 12 and trained staff continually.</p> <p>13 Q But you have not gone back and looked at the 14 questionnaires for all of the case control 15 studies?</p> <p>16 A No, I have not looked at them all. I have looked 17 at the materials and methods in enough detail that 18 I'm confident that they did what they could to 19 reduce recall bias.</p> <p>20 Q But so has everyone else in the world of talc 21 ovarian cancer literature. They have all looked 22 at the methods in the published paper.</p> <p>23 Almost to a fault, everyone is saying that 24 one of the things going on in these talc ovarian 25 cancer is recall bias. Right?</p>
<p>Page 291</p> <p>1 of case control studies helps reduce the amount of 2 recall bias in each individual study. The 3 meta-analysis itself, no.</p> <p>4 Q For these case control studies, for the talc 5 ovarian cancer case control studies, what have you 6 done qualitatively and quantitatively to determine 7 in your mind that those questions are asked in a 8 certain way, you know, such that recall bias is 9 not a problem?</p> <p>10 Have you looked at all of the study 11 questionnaires?</p> <p>12 Have you compared them against the results?</p> <p>13 What have you done?</p> <p>14 I see that you cited the Cramer article on 15 recall bias.</p> <p>16 Have you undertaken a critical analysis of 17 these case control studies to conclude that recall 18 bias is not really a problem?</p> <p>19 MS. PARFITT: Objection. Form.</p> <p>20 A I have looked at each one of these studies at the 21 material and methods and --</p> <p>22 Q In the paper itself?</p> <p>23 A In the paper itself. I have not gone back and 24 looked at questionnaires. I can state I have been 25 doing this for twenty years. I have trained at</p>	<p>Page 293</p> <p>1 That is nearly uniform. It's stated in all 2 of the cohort studies. It's stated in all of the 3 meta-analyses, at least until Woolen.</p> <p>4 This is not a claim that you didn't read.</p> <p>5 You were aware that people are claiming this at 6 least in the literature, correct?</p> <p>7 MS. PARFITT: Objection to form.</p> <p>8 A I would claim that recall bias in case control 9 studies, not even specific to talcum powder and 10 ovarian cancer, that is a potential limitation of 11 the study design of a case control study.</p> <p>12 I would also say that with this particular 13 research question, that the evidence for recall 14 bias is limited. And it is really just limited to 15 the Schildkraut study. And even amongst women 16 that we don't think had a significant exposure, 17 potential to recall bias, you know, there is also 18 the possibility that there was just 19 underreporting.</p> <p>20 That is another possibility that we don't 21 talk about. And if that was the case, we would be 22 misclassifying people and driving these odds 23 ratios towards the null. But saying that case 24 control studies are affected by recall bias is 25 absolutely something that we teach in Epidemiology</p>

<p>Page 294</p> <p>1 101.</p> <p>2 Do we have great evidence of it for this</p> <p>3 particular association? No, we don't.</p> <p>4 Q And so all of the authors of all of the papers</p> <p>5 that do mention that what is going on in some of</p> <p>6 these case control studies is recall bias, all of</p> <p>7 those authors are just wrong?</p> <p>8 MS. PARFITT: Objection. Misstates the</p> <p>9 evidence in this case.</p> <p>10 A I absolutely did not say that. I said that that</p> <p>11 is always a potential for the types of studies --</p> <p>12 case control studies always have the potential for</p> <p>13 recall bias.</p> <p>14 Just like cohort studies always have the</p> <p>15 potential for loss to follow-up, which means you</p> <p>16 don't follow your participants until the end maybe</p> <p>17 for reasons that are very different because they</p> <p>18 are too sick to answer and so forth.</p> <p>19 So there are study design issues inherent to</p> <p>20 all of the types of study designs.</p> <p>21 Q Okay. I'm going to mark as Exhibit 25 the Woolen</p> <p>22 paper.</p> <p>23 (EXHIBIT NUMBER 25 WAS MARKED FOR</p> <p>24 IDENTIFICATION.)</p> <p>25 A Yes.</p>	<p>Page 296</p> <p>1 Q Do you see that?</p> <p>2 A Yes. So they "performed a systematic review of</p> <p>3 the literature with the goal of identifying</p> <p>4 studies that captured data on frequency of use..."</p> <p>5 I am not saying in various ways.</p> <p>6 Q Let me see if I can find that quote.</p> <p>7 A Okay.</p> <p>8 Q The bottom paragraph, "In 2022..." in the third</p> <p>9 sentence you say "Frequency of use was captured</p> <p>10 various ways."</p> <p>11 Do you see that? That is four lines down.</p> <p>12 A From the top of the paragraph?</p> <p>13 Q Yes.</p> <p>14 A Oh, yes. That was across the different studies.</p> <p>15 Can we back up and just go on record as</p> <p>16 correcting this?</p> <p>17 Q Yes.</p> <p>18 A So the sentence prior it should state "Of all</p> <p>19 identified studies, 11 were included in the</p> <p>20 analysis (10 case-control, 1 cohort)."</p> <p>21 Q Got it.</p> <p>22 A I don't know where my numbers went there.</p> <p>23 Yes, frequency of use was captured in various</p> <p>24 ways.</p> <p>25 Q Yes or no, do you have any concerns with the way</p>
<p>Page 295</p> <p>1 Q As we discussed this morning, Smith-Bindman is a</p> <p>2 paid plaintiffs' expert in this MDL talc</p> <p>3 litigation, correct?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 Q Are you aware of that?</p> <p>6 A I believe so, yes.</p> <p>7 Q Okay. Do you know any history behind the efforts</p> <p>8 to publish this paper?</p> <p>9 A I do not.</p> <p>10 Q Do you know if the genesis of this paper was in a</p> <p>11 litigation report?</p> <p>12 A I do not.</p> <p>13 Q Do you know anything about Smith-Bindman's</p> <p>14 experience or qualifications or credentials to</p> <p>15 conduct a meta-analysis?</p> <p>16 A I do not.</p> <p>17 Q Have you ever communicated with any of the authors</p> <p>18 of this paper?</p> <p>19 A No.</p> <p>20 Q Have you reviewed any peer reviewed comments</p> <p>21 associated with this paper?</p> <p>22 A No, I do not. I would not.</p> <p>23 Q On Page 17 of your report, you say that frequency</p> <p>24 of use was captured various ways.</p> <p>25 A Uh-huh.</p>	<p>Page 297</p> <p>1 frequency was captured for this study?</p> <p>2 A I do not because they outlined clearly what their</p> <p>3 intent was in their material and method section.</p> <p>4 Q You note in the report that the only cohort data</p> <p>5 came from NHS I.</p> <p>6 That was from O'Brien, correct?</p> <p>7 A Yes.</p> <p>8 MS. PARFITT: Objection.</p> <p>9 Q You say that had the required frequency of use</p> <p>10 data, correct?</p> <p>11 A I don't know -- yes. Yes.</p> <p>12 Q To be clear, when you say required, you mean</p> <p>13 required by the author's parameters?</p> <p>14 A Yes. With respect to some measure of frequency.</p> <p>15 Q Is it correct that by imposing that measurement</p> <p>16 requirement the only data that could have possibly</p> <p>17 been used from the cohort data was the NHS I data</p> <p>18 because it allowed subjects to answer if they use</p> <p>19 powder daily?</p> <p>20 Do you know that?</p> <p>21 A I don't know that to be certain.</p> <p>22 Q That is the only cohort group that would be</p> <p>23 defined as at least two times per week, did you</p> <p>24 know that?</p> <p>25 A I believe that to be true as I think Women's</p>

<p style="text-align: right;">Page 298</p> <p>1 Health Initiative just captured duration versus 2 frequency.</p> <p>3 Q The effect of the requirement by the authors was 4 to, had the effect of excluding all of the cohort 5 data except the NHS I data, correct?</p> <p>6 MS. PARFITT: Objection to form.</p> <p>7 A That was based on how they defined, you know, what 8 sort of exposure data that they needed. Yes, it 9 had that effect.</p> <p>10 But it also, you know, excluded a large 11 number of case control studies as well. There 12 were forty-one studies excluded. From the 13 fifty-two that they started with, they went down 14 to eleven.</p> <p>15 So it excluded, you know, a large portion of 16 the case control as well.</p> <p>17 Q Did you notice what the authors did when they 18 cited a paper that had multiple ORs that met the 19 parameters of the paper?</p> <p>20 Did you critically evaluate that?</p> <p>21 A Yeah. I believe it was stated as how they 22 extracted the data, that they reported the highest 23 talc use used.</p> <p>24 Q The highest odds ratio?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 300</p> <p>1 In that report there was a dose response with 2 increasing risk with increasing frequency of 3 talcum powder used with the hazard ratio of 1.4 4 for daily users. Confidence interval 1.7 to 1.68 5 for daily users.</p> <p>6 I think really they are just using that as 7 data to compare to their pooled meta-analysis.</p> <p>8 Q Right. My question was, do they explain why they 9 used the patent finding only from NHS I, but not 10 any other subgroup findings for the other 11 studies?</p> <p>12 A No, they do not describe why they do that. Other 13 than to say that it was the highest frequency of 14 use. So, no.</p> <p>15 Q Again, to be clear, they subsetted it even more. 16 They didn't just do highest frequency. They did 17 highest frequency patent only, correct?</p> <p>18 MS. PARFITT: Objection. Form.</p> <p>19 A It appears that way for, yes, for that analysis.</p> <p>20 Q Do you know that the NCI PDQ refers to this study 21 as having a highly selected subset analyses?</p> <p>22 A Yes, I am aware.</p> <p>23 Q Do you know that the NCI PDQ notes that because of 24 the structure of the Woolen analysis the results 25 should be interpreted with care?</p>
<p style="text-align: right;">Page 299</p> <p>1 Q Not the highest talc use. Were you aware that 2 they picked -- any paper that they came across 3 with multiple ORs that could have been used to 4 meet their parameters, are you aware that they 5 picked the highest OR?</p> <p>6 MS. PARFITT: Objection. Misstates the 7 evidence in the case.</p> <p>8 A What I'm aware that they selected was based on how 9 they say they extracted their data, which is when 10 duplicate reports of the same subjects were 11 published, the publication reporting the highest 12 talc use was selected.</p> <p>13 Q Did they restrict any of the other data sets to 14 patent only like they did with NHS I data?</p> <p>15 A I'm not sure that I saw the analysis in here. No.</p> <p>16 Q Did you answer, or are you still looking?</p> <p>17 A I'm still looking. Thank you. I don't believe 18 they -- they have a discussion of the O'Brien 19 findings.</p> <p>20 What I'm looking at right now is 2531 in kind 21 of the middle of the left-hand column. They talk 22 about the patent twos with respect to the odds 23 ratio. They note that when O'Brien limited women 24 with patent fallopian tubes, the hazard was 1.13 25 for ever versus never.</p>	<p style="text-align: right;">Page 301</p> <p>1 MS. PARFITT: Objection. Form.</p> <p>2 A Yes. I believe we covered that this morning. But 3 the PDQ is -- it's not all of the National Cancer 4 Institute. It is --</p> <p>5 Q That was not my question.</p> <p>6 MS. PARFITT: Let her finish.</p> <p>7 Q It was strictly limited to the PDQ.</p> <p>8 A The PDQ does not represent the NCI. It is a --</p> <p>9 Q That is not my question.</p> <p>10 A -- subgroup of the --</p> <p>11 Q We are running out of time. That is not my 12 question.</p> <p>13 MS. PARFITT: Let her finish the answer or 14 it will be a bad record. We have two people 15 talking.</p> <p>16 A So, yes, the PDQ says that this is a highly 17 selective study, which the authors acknowledge and 18 announce in their materials and methods. They 19 are -- it should be interpreted with caution 20 because, indeed, it's the only study of its kind.</p> <p>21 This is from a group of people that put out 22 the NCI PDQ, which is not the mouthpiece of the 23 entire NCI.</p> <p>24 Q At least the editorial board members of the 25 NCI PDQ when they commented on the Woolen paper</p>

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<p style="text-align: right;">Page 302</p> <p>1 their comment was that the results of the paper 2 should be interpreted with care. 3 That was their comment, correct? 4 MS. PARFITT: Objection to form. 5 A Correct, that was their comment. 6 Q That is the PDQ that Karmanos links to, ACR links 7 to, correct? 8 We looked at that this morning. 9 MS. PARFITT: Objection. Form. 10 Q That is yes or no. 11 A Yes. 12 Q Do you agree that the hospital-based case control 13 studies do not show statistically significant 14 associations? 15 A I would need to go back and look at my list of 16 hospital-based studies in case control. 17 Q I will just withdraw the question. 18 A Okay. 19 Q Do you think hospital-based case control studies 20 have any advantages over population-based case 21 control studies? Yes or no? 22 A No. 23 MR. JAMES: Off the record. 24 (OFF RECORD AT 5:20 P.M.) 25 (AT THIS TIME A SHORT RECESS WAS HELD OFF</p>	<p style="text-align: right;">Page 304</p> <p>1 in dose. 2 It would be really difficult to discern that 3 because a lot of women, they use multiple forms. 4 They use -- it's hard to disentangle one from the 5 other. 6 And the number of diaphragm users is very, 7 very low compared to the women who are using it 8 overall. 9 So the biological plausibility, what I look 10 at was just general genital use of talcum powder. 11 Q For recall bias, did recall bias -- I know you 12 testified about the evidence from the Schildkraut 13 study, correct? 14 A Yes. Correct. 15 Q Does recall bias exist in the studies for reasons 16 other than media attention or litigation news that 17 onset in 2014? 18 A Could recall bias with -- referring to talc use? 19 Q Correct. 20 A Be impacted by other factors? Potentially, yes. 21 But I can't think of any other factors that 22 might drive that sort of, that sort of 23 association. We do ask in these questionnaires 24 about so many other exposures. Part of that is so 25 that we are not -- we never disclose to a person</p>
<p style="text-align: right;">Page 303</p> <p>1 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS 2 WERE HAD:) 3 (ON RECORD AT 5:22 P.M.) 4 BY MR. JAMES: 5 Q Sitting here today do you know if the studies that 6 have evaluated the association between talc on 7 diaphragms and sanitary napkins show a 8 statistically significant association with ovarian 9 cancer? 10 A I did not look at that subset of women. I didn't 11 look at the exact usage in the genital area. So, 12 no. 13 I do know some studies collected that level 14 of detailed data. 15 Q Do you believe that the application of talcum 16 powder on diaphragms or sanitary napkins could be 17 more biologically relevant for your plausibility 18 hypothesis than perineal application? 19 MS. PARFITT: Objection. Form. 20 Answer if you can. 21 A I don't think there is data to support that. When 22 I think about it from a biological standpoint 23 perhaps, you know, diaphragm use, just because 24 it's inserted internally, if it was dusted with 25 talcum powder perhaps there would be a difference</p>	<p style="text-align: right;">Page 305</p> <p>1 participating in our studies what the exact 2 hypotheses are. 3 We are generally interested in learning why 4 one person develops ovarian cancer versus another. 5 We ask a wide range of things to help reduce the 6 risk of recall bias. 7 Q One of the points that you make in your report 8 about recall bias is that recall bias might exist 9 if the exposure event is one that could be 10 considered sensitive. 11 Do you recall making that comment? 12 A Yes. 13 Q Is it your contention that women would not find 14 the application of talcum powder to the perineal 15 area to be a sensitive topic? 16 A Correct. 17 Q You do not think that is a sensitive -- 18 A I do not think that that is a sensitive issue. 19 Q You also, in commenting on recall bias with 20 Cramer, you do discuss Cramer's 2016 paper in 21 regard to recall bias, correct? 22 A Right. 23 Q One of the launching points in your report from 24 that paper is that there is no recall bias or 25 recall bias might be discounted or whatever</p>

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<p>1 because there is no association with non-genital 2 talc use.</p> <p>3 Do you recall that being one of Cramer's 4 points?</p> <p>5 A I'm looking at his points right here at the top of 6 Page 28?</p> <p>7 Q Yes.</p> <p>8 A So this was the most recent Cramer paper.</p> <p>9 Q Reason Number 2. Do you see that there?</p> <p>10 A Yes. These were, this was a discussion provided 11 by Cramer about recall bias.</p> <p>12 Q You said you agree with them?</p> <p>13 A Yes. I'm in agreement with that explanation as a 14 whole.</p> <p>15 Q Understood. With just respect to point two, you 16 do, in fact, understand that there are studies 17 that report associations with non-genital use 18 including Schildkraut, correct?</p> <p>19 A Correct. Yes.</p> <p>20 Q Let's go to your Bradford Hill analysis.</p> <p>21 A Okay.</p> <p>22 Q That is Page 35.</p> <p>23 A Yes. That is the introduction, I believe.</p> <p>24 Q I'm getting close to the end and my time is almost 25 up.</p>	<p>1 A Correct.</p> <p>2 Q Do you think strength standing alone by itself as 3 its own factor is an important factor to consider?</p> <p>4 A I do.</p> <p>5 Q Do you think strength in the talc ovarian cancer 6 literature is met?</p> <p>7 A I do.</p> <p>8 Q But you will not, you do not, do you refer to the 9 1.25 association that you claim as strong?</p> <p>10 A So that is a single point estimate. I would say 11 that the strength of the associations, the 12 positive associations as a whole are strong.</p> <p>13 The one study that points to a 1.25 would not 14 be enough for me to say that single one is strong.</p> <p>15 Again, that goes into the labeling of a 16 single point estimate on some sort of scale which 17 I don't intend to do.</p> <p>18 Q At the bottom of that section you say in the 19 second to last sentence, "This effect is not 20 diminished whatsoever by the strength of the 21 association."</p> <p>22 Do you see that sentence?</p> <p>23 A Yes.</p> <p>24 Q And can you briefly tell me what you mean by that?</p> <p>25 A Yes. So when I talk about the effect, I'm</p>
Page 307	Page 309
<p>1 A All right.</p> <p>2 Q So with respect to your Bradford Hill analysis, 3 you note on Page 36, "Hill noted that the first 4 two considerations, strength of association and 5 consistency could be considered together."</p> <p>6 Do you see that sentence?</p> <p>7 A Yes, I do.</p> <p>8 Q Are you contending that that statement is in 9 Hill's 1965 paper?</p> <p>10 A It's perhaps not directly quoted, but strength of 11 association and consistency of the studies have 12 similar underpinnings.</p> <p>13 You would use similar data to assess that.</p> <p>14 Consistency would be how consistent is the point 15 estimate across a various number of studies. So 16 the strength of the association is based on those 17 point estimates.</p> <p>18 Q Okay. My real precise question here, is Hill your 19 authority for the proposition that strength and 20 consistency can be considered together?</p> <p>21 That is what you are referring to here?</p> <p>22 A Yes.</p> <p>23 Q The Bradford Hill analysis, strength is one 24 factor. Consistency is another factor to 25 consider, correct?</p>	<p>1 referring to, I think, the sentence before it.</p> <p>2 When I talk about just even that simple never ever 3 measure of perineal talc and the association with 4 ovarian cancer was nearly constant regardless of 5 study population, decade of study enrollment, and 6 race and ethnicity.</p> <p>7 So then I go on to say, "This effect is not 8 diminished whatsoever by the strength of the 9 association."</p> <p>10 Just because the point estimate seen in those 11 various studies was not 5.2 or 3.7 it does not 12 diminish the fact that there is still a strength 13 of association there and that the consistency, I 14 think, is very, very strong.</p> <p>15 Q Do you agree that Hill recognized that for 16 consistency a great deal of weight should be 17 placed upon different study designs showing the 18 same results?</p> <p>19 A I'm not sure I took that from Hill's original work 20 in 1965.</p> <p>21 Q Just real quick I will mark Hill as whatever our 22 last exhibit was.</p> <p>23 (EXHIBIT NUMBER 26 WAS MARKED FOR 24 IDENTIFICATION.)</p> <p>25 Q For Hill on Page 9, the left column top --</p>

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Page 310	Page 312
1 A Yes.	1 necessarily a strong factor because we are
2 Q -- this is in discussing Consistency. That starts	2 starting to learn that, you know, as we learn more
3 on Page 8 and it rolls to Page 9.	3 about biology, specificity is not as strong of an
4 He says, "I would myself put a good deal of	4 element.
5 weight upon similar results reached in quite	5 You know, certain things, even like biologic
6 different ways, e.g. prospectively and	6 plausibility, you need to have some understanding
7 retrospectively."	7 of the basic biological underpinnings. Sometimes
8 Do you see that?	8 our basic science just has not caught up yet.
9 A Yes.	9 MR. JAMES: I'm saving myself four
10 Q He is referring to consistency among study design	10 minutes.
11 correct?	11 MS. PARFITT: We will take a brief break.
12 A Yes.	12 (OFF RECORD AT 5:40 P.M.)
13 Q Do you agree with that, that one component of	13 (AT THIS TIME A SHORT RECESS WAS HELD OFF
14 consistency is consistency among or between study	14 THE RECORD AFTER WHICH THE FOLLOWING PROCEEDINGS
15 designs?	15 WERE HAD:)
16 A Not necessarily because as we have been stating	16 MR. JAMES: For the record correction,
17 all day, there are strengths and limitations to	17 Exhibit 24 is the O'Brien review article.
18 each of these study designs.	18 Exhibit 25 is Woolen. Exhibit 26 is
19 I would not say a prospective study to	19 Bradford Hill.
20 examine the association between an exposure that	20 ON RECORD AT 5:50 P.M.)
21 potentially happens early in life and a disease of	21 EXAMINATION
22 very late onset that is relatively rare is an	22 QUESTIONS BY MS. PARFITT:
23 ideal study for a prospective study. That is	23 Q Dr. Cote, I just have a few questions for you.
24 better suited to a retrospective study.	24 What I would like you to do is reference now
25 With that said, I don't think the cohort	25 Pages 13 and 14 of your report and the section
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1 evidence in this particular analysis that I have	1 entitled Biologic Mechanisms Linking Perineal Talc
2 laid out here today differs from the case control	2 and Ovarian Cancer.
3 studies. The point estimates may differ. Overall	3 Are you there?
4 the positive association exists.	4 A Yes.
5 Q Last question, on Page 6 of your report -- I will	5 Q You were asked by counsel several questions with
6 try to reserve three minutes.	6 regard to articles that you reviewed for purposes
7 Please go to Page 6 of your report.	7 of your opinion in the areas of invitro studies,
8 A I'm there.	8 invitivo studies, and cellular studies.
9 Q Throughout your Bradford Hill analysis you	9 Do you remember that many, many hours ago?
10 conclude each section, or most of the sections,	10 A Yes, I do.
11 with commentary.	11 Q All right. What is the significance, if any, of
12 For example with strength you say, I give	12 your review of these invitro, invitivo, and cellular
13 strong weight to strength. In some instances you	13 studies to your causation opinion?
14 say, I give, you know, low weight or something	14 A It's really right there in the title. It is the
15 like that.	15 biologic mechanism piece of this trying to show
16 A Yes.	16 that, yes, indeed, something kind of at the entry
17 Q My question is for each of the factors when you	17 of the female genital tract can move up that
18 provide that description are you saying that you	18 tract.
19 find the evidence strongly supports that factor,	19 Things that -- there's that scientific word
20 or are you saying methodologically you find that	20 "things" again -- particles, materials, foreign
21 factor to be important in a causal analysis?	21 objects, including something like talc, can then
22 A I find it the latter. From a methodology	22 move into various tissues in the female
23 standpoint certain of these factors, including	23 reproductive tract, whether that be the tissues
24 specificity, because it's right in front of me,	24 surrounding the fallopian tubes into the ovaries
25 even Hill, himself, says specificity is not	25 and so forth.

<p style="text-align: right;">Page 314</p> <p>1 And by nature of the fact that talc does not 2 disintegrate, that it can eventually produce 3 chronic inflammatory response. We see that with, 4 you know, bringing macrophages and those sorts of 5 things into the tissue. And that immune response 6 starts a cascade of other sorts of cancer-related 7 hallmarks of cancer and things that we know cancer 8 cells do, like proliferation. We know they try to 9 avoid the immune system. There is less apoptosis. 10 So those sorts of things. 11 So it was really trying to build this 12 biological mechanism as part of the Bradford Hill 13 analysis as to how could talc be associated with 14 ovarian cancer? 15 What is the underlying biological mechanism? 16 Q You were asked several questions, again, hours ago 17 with regard to issues pertaining to asbestos and 18 it's association with ovarian cancer and also 19 fibrous talc and it's association with ovarian 20 cancer. 21 What, if anything, significance based upon 22 your research and your opinions today does 23 asbestos and fibrous talc, how does that add, if 24 it does, to your causation opinions in this case? 25 MR. JAMES: Objection to form.</p>	<p style="text-align: right;">Page 316</p> <p>1 A Talc without asbestiform fibers. 2 Q Okay. Was the talc that was reviewed in 2010 talc 3 that contained asbestos? 4 MR. JAMES: Objection to the form. 5 A No. That was what was reviewed later. It's 6 earlier in the report. I should have done this 7 opposite. 8 That is what was reviewed in 2012. So 2010 9 was talc without asbestos. 10 Q Dr. Cote, did any of the questions raised by 11 counsel for Johnson & Johnson today throughout the 12 seven hours of questioning change the opinions 13 which you will be sharing with the jury and the 14 court in this case that talcum powder use in the 15 genital area can cause ovarian cancer? 16 MR. JAMES: Objection to form, please. 17 A No. There is nothing we have discussed today that 18 changes the overall opinions contained in my 19 expert report. 20 Q Okay. 21 MS. PARFITT: That is all that I have. 22 Thank you. 23 EXAMINATION 24 QUESTIONS BY MR. JAMES: 25 Q One follow-up, I think, in my four minutes.</p>
<p style="text-align: right;">Page 315</p> <p>1 A Okay. So it goes back also to the biological 2 mechanism. It adds in the IARC reports -- and I'm 3 looking at my statements right now. The most 4 recent monograph was the one that focused on 5 Group 1 carcinogens that included talc that may 6 form fibers that are asbestiform in habit and that 7 type of talc referred to as fibrous talc had been 8 classified by IARC as a Class 1 human carcinogen. 9 That was the Group 1 analysis in 2012. In 10 2010 it was -- the overall conclusion of the 11 report was that use of, perineal use of talc-based 12 powder is possibly carcinogenic to humans. That 13 was the Group 2B. 14 Again, it's just more biologic plausibility. 15 Q The 2010 monograph, what was the agent that was 16 reviewed? 17 Was it talcum powder? 18 Was it talcum powder with asbestos? 19 Was it talcum powder without asbestos? 20 What was the agent reviewed by the working 21 group back in 2010? 22 MR. JAMES: Objection to form, please. 23 A This report, again, right from my notes focused on 24 talc that did not contain asbestiform fibers. 25 Q Okay.</p>	<p style="text-align: right;">Page 317</p> <p>1 Did you look at any studies dealing with talc 2 minors or millers? 3 Have you ever looked at any of those studies? 4 A I think a lot of that information was included in 5 both the IARC reports as well as Health Canada. I 6 did not focus at all on occupational studies with 7 respect to ovarian cancer. 8 Q Okay. 9 MR. JAMES: That will be it. Thank you 10 for your time. 11 A No. Thank you. 12 MS. PARFITT: We will read and execute 13 signature. Thank you. 14 (OFF RECORD AT 5:57 P.M.) 15 16 17 AND FURTHER DEPONENT SAITH NOT 18 19 20 MICHELE L. COTE, PH.D., M.P.H. 21 22 23 24 25</p>

1 STATE OF INDIANA) 2) SS: 3 COUNTY OF BOONE) 4 I, Wendi Kramer Sulkoske, Notary Public in and 5 for said county and state, do hereby certify that 6 MICHELE L. COTE, PH.D., M.P.H. the deponent herein 7 was by me first duly sworn to tell the truth in 8 the aforementioned matter; 9 That the foregoing deposition was taken on 10 behalf of the Defendants at the time and place 11 heretofore mentioned with counsel present as 12 noted. 13 That the deposition was taken down in 14 Stenograph notes, reduced to typewriting under 15 my direction, is a true record of the testimony 16 given by said deponent, and was thereafter 17 presented to the deponent for signature. 18 That this certificate does not purport to 19 acknowledge or verify the signature hereto of 20 the deponent. 21 I do further certify that I am a 22 disinterested person in this cause of action; 23 that I am not a relative or attorney of any of 24 the parties or otherwise interested in the event 25 of this action, and am not in the employ of the	Page 318
1 attorneys for the respective parties. 2 IN WITNESS WHEREOF, I have hereunto set my 3 hand and affixed my notarial seal this 1st 4 day of April, 2024. 5 6 <%1316,Signature%> 7 _____ 8 Wendi Kramer Sulkoske, Notary Public 9 10 Commission Number NP0661030 11 My commission expires December 1, 2030. My County of residence is Boone. 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 319

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate.

The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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